Vol.42—No.50
3-15-77

BOOK 2:
PAGES
14301-14669

federal register

BOOK 2 OF 2 BOOKS

TUESDAY, MARCH 15, 1977

PART V

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

FOOD FOR HUMAN CONSUMPTION

Reorganization and Republication

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Recodification Docket No. 15; Docket No. 76N-0501]

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

REORGANIZATION AND REPUBLICATION

The Food and Drug Administration (FDA) is reorganizing and republishing certain sections of the general regulations together with the human food regulations under its jurisdiction, effective March 15, 1977.

The Commissioner of Food and Drugs, for the purposes of establishing an orderly development of informative regulations for the Food and Drug Administration, furnishing ample room for expansion of such regulations in years ahead, and providing the public and affected industries with regulations that are easy to find, read, and understand, has initiated a recodification program for Chapter I of Title 21 of the Code of Federal Regulations.

This is the fifteenth document in a series of recodification documents that will eventually include all regulations administered by FDA; this document incorporates certain general regulations applicable to human food formerly under Subchapter A into the newly organized Subchapter B but does not set forth those regulations administered by the Environmental Protection Agency under Part 193. The full text of Part 193, transferred from Part 121, was set out under Part 123 in the tenth recodification document published in the FEDERAL REGISTER of March 28, 1975 (40 FR 14156); Part 123 was subsequently transferred to Part 193 by publication in the FEDERAL REGISTER of June 28, 1976 (41 FR 26565).

The fourteenth recodification document, published in the FEDERAL REGISTER of September 10, 1976 (41 FR 38618), transferred § 1.16 and all of Subpart C of Part 121 to Subchapter E—Animal Drugs, Feeds, and Related Products. Upon publication of this fifteenth recodification document, all regulations concerning human food now appear under reorganized Subchapter B (Parts 100 through 199). The fourteenth recodification document also transferred all other animal food regulations from old Subchapter B to Subchapter E (Parts 500 through 599). At that time, separation of regulations concerning animal food from those on human food necessitated some duplication (with changes for editorial clarification) of certain sections in Subchapter B and Subchapter E. The reader will find all the other "old sections" listed in the redesignation table appearing in the preamble to the September 1976 recodification listed again in the redesignation table below, reflecting their position in Subchapter B number-keyed, as far as practicable, to their section number in Subchapter E (e.g., § 1.7, as applicable to animal food, was redesignated as § 501.1 and, as applicable to human foods, is redesignated below as § 101.1).

Changes in the food additive numbering system in this recodification have been made in an effort to provide a comprehensive system to solve the problems of clarity and accessibility. The Commissioner invites suggestions for further improvement to make the food additive regulations clear and readily accessible to the reader.

The following table shows the relationship of the CFR section numbers formerly under Subchapter A and those sections being redesignated under the reorganized Subchapter B and under Subchapter E. This conversion table includes all changes made by FDA recodification documents numbered 14 and 15.

Old section	New human section	New animal section [1]
1.7	101.1	501.1
1.8	101.3	501.3
1.8a	101.5	501.5
1.8b	101.105	501.105
1.8c	101.8	501.8
1.8d	101.2	501.2
1.9	101.15	501.15
1.10	101.4	501.4
1.10a	101.100	501.100
1.10b	101.103	501.103
1.12	101.22	501.22
1.13	101.17	501.17
1.15	101.18	501.18
1.16	NA	501.110
1.17	101.9	NA
1.18	101.25	NA
3.2	100.150	NA
3.5	100.135	NA
3.17	166.40	NA
3.19	133.10	NA
3.20	100.160	NA
3.23	101.35	NA
3.24	100.145	NA
3.31	100.140	NA
3.38	161.30	NA
3.51	101.33	NA
3.69	100.120	NA
3.72	100.130	NA
3.87	100.155	NA
3.88	101.6	NA
3.93	109.15	509.15
3.202	101.29	NA
3.206	131.25	NA
3.207	101.10	NA
10.1	130.3	564.3
10.2	130.5	564.5
10.3	130.8	564.8
10.4	130.20	564.20
10.5	130.17	564.17
10.6	130.12	564.12
10.7	130.14	564.14
10.8	130.6	564.6
11.1	103.5	NA
11.2	103.3	NA
11.5	103.23	NA
11.6	103.29	NA
11.7	103.35	NA
14.1	163.110	NA
14.2	163.111	NA
14.3	163.112	NA
14.4	163.113	NA
14.5	163.114	NA
14.6	163.123	NA
14.7	163.130	NA
14.8	163.140	NA
14.9	163.135	NA
14.10	163.145	NA
14.11	163.153	NA
14.12	163.150	NA
14.13	163.155	NA
14.14	163.117	NA
15.1	137.105	NA
15.10	137.165	NA
15.20	137.155	NA
15.30	137.160	NA
15.40	137.220	NA
15.50	137.180	NA
15.60	137.185	NA
15.70	137.175	NA
15.75	137.170	NA
15.80	137.200	NA
15.90	137.205	NA
15.100	137.225	NA
15.110	137.195	NA
15.120	137.190	NA
15.130	137.300	NA
15.140	137.305	NA
15.150	137.320	NA
15.500	137.250	NA
15.501	137.275	NA
15.502	137.255	NA
15.503	137.280	NA
15.504	137.265	NA
15.505	137.285	NA
15.506	137.270	NA
15.507	137.290	NA
15.508	137.211	NA
15.509	137.215	NA
15.510	137.230	NA
15.511	137.245	NA
15.512	137.240	NA
15.513	137.260	NA
15.514	137.235	NA
15.525	137.350	NA
16.1	139.110	NA
16.2	139.120	NA
16.3	139.138	NA
16.4	139.140	NA
16.5	139.125	NA
16.6	139.150	NA
16.7	139.180	NA
16.8	139.160	NA
16.9	139.115	NA
16.10	139.155	NA
16.11	139.135	NA
16.12	139.165	NA
16.13	139.121	NA
16.14	139.122	NA
16.15	139.117	NA
17.1	136.3	NA
17.10	136.110	NA
17.20	136.115	NA
17.30	136.130	NA
17.40	136.160	NA
17.50	136.180	NA
17.60	136.165	NA
18.1	131.3	NA
18.2	131.110	NA
18.10	131.135	NA
18.20	131.145	NA
18.30	131.180	NA
18.501	131.155	NA
18.511	131.157	NA
18.515	131.150	NA
18.520	131.130	NA
18.525	131.115	NA
18.530	131.120	NA
18.540	131.125	NA
18.545	131.127	NA
18.550	131.160	NA
18.555	131.162	NA
18.560	131.185	NA
18.565	131.187	NA
18.570	131.164	NA
18.575	131.189	NA
19.499	133.3	NA
19.500	133.113	NA
19.502	133.114	NA
19.503	133.116	NA
19.505	133.136	NA
19.507	133.137	NA
19.510	133.118	NA
19.512	133.119	NA
19.513	133.121	NA
19.515	133.133	NA
19.520	133.162	NA
19.525	133.129	NA
19.530	133.128	NA
19.531	133.131	NA
19.535	133.144	NA
19.537	133.145	NA
19.540	133.195	NA
19.542	133.196	NA
19.543	133.149	NA
19.544	133.185	NA
19.545	133.108	NA
19.547	133.109	NA
19.550	133.160	NA
19.551	133.161	NA
19.555	133.138	NA
19.560	133.142	NA
19.565	133.106	NA
19.567	133.141	NA
19.569	133.164	NA
19.570	133.184	NA
19.575	133.152	NA
19.580	133.153	NA
19.585	133.154	NA
19.590	133.181	NA
19.591	133.111	NA
19.595	133.165	NA
19.600	133.155	NA
19.601	133.157	NA
19.605	133.156	NA
19.606	133.158	NA
19.610	133.183	NA
19.615	133.102	NA
19.620	133.103	NA
19.625	133.104	NA
19.635	133.127	NA
19.637	133.186	NA
19.639	133.140	NA
19.650	133.150	NA
19.655	133.187	NA
19.660	133.188	NA

See footnotes at end of table.

Old section	New human section	New animal section [1]
19.665	133.182	NA
19.670	133.190	NA
19.675	133.191	NA
19.680	133.148	NA
19.685	133.189	NA
19.750	133.169	NA
19.751	133.167	NA
19.755	133.170	NZ
19.760	133.171	NA
19.763	133.168	NA
19.765	133.173	NA
19.770	133.174	NA
19.775	133.179	NA
19.776	133.175	NA
19.780	133.180	NA
19.781	133.176	NA
19.782	133.134	NA
19.783	133.178	NA
19.785	133.123	NA
19.787	133.124	NA
19.788	133.125	NA
19.790	133.147	NA
19.791	133.146	NA
19.792	133.193	NA
20.1	135.30	NA
20.2	135.10	NA
20.3	135.40	NA
20.4	135.20	NA
20.5	135.90	NA
20.6	135.65	NA
20.7	135.70	NA
20.8	135.50	NA
22.1	169.3	NA
22.2	169.175	NA
22.3	169.176	NA
22.4	169.177	NA
22.5	169.178	NA
22.6	169.180	NA
22.7	169.181	NA
22.8	169.179	NA
22.9	169.182	NA
25.1	169.140	NA
25.2	169.115	NA
25.3	168.150	NA
26.1	168.111	NA
26.2	168.110	NA
26.3	168.120	NA
26.4	168.121	NA
26.5	168.122	NA
27.1	145.3	NA
27.1 except (g) through (n) and (o) (1) and (4).	146.3	NA
27.2	145.170(a)	NA
27.3	145.170(b)	NA
27.4	145.170(c)	NA
27.5	145.173	NA
27.6	145.171	NA
27.10	145.115(a)	NA
27.11	145.115(b)	NA
27.12	145.115(c)	NA
27.13	145.118	NA
27.14	145.116	NA
27.15	145.190	NA
27.20	145.175(a)	NA
27.21	145.175(b)	NA
27.22	145.175(c)	NA
27.23	145.178	NA
27.24	145.176	NA
27.25	145.140	NA
27.30	145.125(a)	NA
27.31	145.125(b)	NA
27.32	145.125(c)	NA
27.33	145.128	NA
27.34	145.126	NA
27.35	145.120	NA
27.40	145.135(a)	NA
27.41	145.135(b)	NA
27.42	145.135(c)	NA
27.43	145.136	NA
27.45	145.185(a)	NA
27.46	145.185(b)	NA
27.47	145.185(c)	NA
27.50	145.180(a)	NA
27.51	145.180(b)	NA
27.52	145.180(c)	NA
27.54	146.185(a)	NA
27.55	146.185(b)	NA
27.56	146.185(c)	NA
27.57	145.181	NA
27.60	146.187	NA
27.70	145.130	NA
27.71	145.134	NA
27.73	145.131	NA
27.80	145.110(a)	NA
27.81	145.110(c)	NA
27.90	145.145(a)	NA
27.91	145.145(b)	NA
27.92	145.145(c)	NA
27.99	146.115	NA
27.100	146.125	NA
27.101	146.120	NA
27.102	146.126	NA
27.103	146.121	NA
27.105	146.135	NA
27.106	146.137	NA
27.107	146.140	NA
27.108	146.141	NA
27.109	146.146	NA
27.110	146.150	NA
27.111	146.145	NA
27.112	146.151	NA
27.113	146.152	NA
27.114	146.153	NA
27.115	146.154	NA
27.125	146.133	NA
27.126	146.113	NA
27.127	146.110	NA
27.128	146.111	NA
27.131	146.130	NA
27.150	146.168	NA
27.151	146.169	NA
27.152	146.170	NA
27.153	146.171	NA
27.154	146.172	NA
27.155	146.175	NA
27.156	146.176	NA
27.157	146.177	NA
27.158	146.155	NA
27.159	146.156	NA
27.160	146.158	NA
27.161	146.159	NA
27.162	146.160	NA
27.163	146.161	NA
27.164	146.163	NA
27.165	146.164	NA
27.166	146.165	NA
27.167	146.166	NA
27.168	146.167	NA
28.1	152.126(a)	NA
28.2	152.126(b)	NA
29.1	150.110	NA
29.2	150.140	NA
29.3	150.160	NA
29.4	150.141	NA
29.5	150.161	NA
30.1	168.180	NA
30.2	168.140	NA
30.3	168.130	NA
30.4	168.160	NA
31.1	165.175	NA
36.3	161.173(c)	NA
36.5	161.145(a)	NA
36.6	161.145(c)	NA
36.10	161.130	NA
36.11	161.131	NA
36.12	161.132	NA
36.13	161.133	NA
36.14	161.134	NA
36.15	161.135	NA
36.16	161.136	NA
36.17	161.137	NA
36.18	161.138	NA
36.19	161.139	NA
36.20	161.140	NA
36.30	161.175	NA
36.31	161.176	NA
37.1	161.190(a)	NA
37.3	161.190(c)	NA
37.10	161.170(a)	NA
37.12	161.170(c)	NA
42.1	160.100	NA
42.10	160.115	NA
42.20	160.110	NA
42.30	160.105	NA
42.40	160.180	NA
42.50	160.190	NA
42.60	160.185	NA
42.70	160.140	NA
42.71	160.150	NA
42.72	160.145	NA
45.1	166.110	NA
46.1	164.150	NA
46.51	164.110	NA
46.52	164.120(c)	NA
50.1	158.3	NA
50.2	158.170(a)	NA
50.3	158.170(b)	NA
51.1	155.170(a)	NA
51.2	155.170(b)	NA
51.3	155.170(c)	NA
51.4	155.172(a)	NA
51.5	155.172(b)	NA
51.6	155.172(c)	NA
51.10	155.120(a)	NA
51.11	155.120(b)	NA
51.20	155.130(a)	NA
51.21	155.130(b)	NA
51.22	155.130(c)	NA
51.30	155.131(a)	NA
51.32	155.131(c)	NA
51.503	155.201(c)	NA
51.990	155.200	NA
53.1	156.145	NA
53.5	156.147	NA
53.10	155.194	NA
53.20	155.192	NA
53.30	155.191	NA
53.40	155.190(a)	NA
53.41	155.190(b)	NA
53.42	155.190(c)	NA
80.1	105.85	NA
85.1	197.810	NA
85.2	197.812	NA
85.3	197.820	NA
85.4	197.825	NA
85.5	197.829	NA
85.6	197.830	NA
85.7	197.840	NA
85.8	197.850	NA
85.9	197.855	NA
85.10	197.860	NA
85.11	197.870	NA
85.12	197.880	NA
85.13	197.885	NA
85.14	197.815	NA
85.16	197.310	NA
85.17	197.312	NA
85.18	197.320	NA
85.19	197.325	NA
85.20	197.329	NA
85.21	197.330	NA
85.22	197.340	NA
85.23	197.350	NA
85.24	197.355	NA
85.25	197.360	NA
85.26	197.370	NA
85.27	197.380	NA
85.28	197.385	NA
85.29	197.315	NA
90.1	108.3	508.3
90.2	108.19	508.19
90.3	108.5	508.5
90.4	108.7	508.7
90.5	108.10	508.10
90.6	108.6	508.6
90.7	108.12	508.12
90.20	108.35	508.35
100.1	104.5	NA
100.2	104.19	NA
100.5	104.47	NA
102.1	102.5	502.5
102.2	102.19	502.19
102.5	102.54	NA
102.6	102.57	NA
102.7	102.50	NA
102.8	102.47	NA
102.9	102.32	NA
102.10	102.30	NA
102.11	102.26	NA
102.12	102.28	NA
102.13	102.39	NA
102.14	102.45	NA
102.15	102.49	NA
102.16	102.55	NA
102.17	102.41	NA
102.19	102.37	NA
121.1	170.3	[2] 570.3
121.2	170.19	570.19
121.3	170.30	570.30
121.4	170.18	570.18
121.5	170.22	570.22
121.6	170.20	570.20
121.8	170.10	NA
121.10	170.45	NA
121.11	170.6	570.6
121.12	170.50	NA
121.13	170.60	NA
121.14	181.5	NA
121.40	170.35	570.35
121.41	170.38	570.38
121.51 except (k) and (l).	171.1	571.1
121.51 (k) and (l).	171.100	571.100
121.52	171.7	571.7
121.53	171.6	571.6
121.54	171.102	571.102
121.55	171.110	571.110
121.72	170.15	570.15
121.74	171.130	571.130
121.75	170.17	570.17
121.101 except table in (d) and (e) through (i).	182.1	582.1
121.101(d)	182.1005	582.1005
	182.1009	582.1009
	182.1033	582.1033
	182.1045	NA
	182.1047	NA
	182.1057	582.1057
	182.1061	582.1061
	182.1069	582.1069
	182.1073	582.1073
	182.1077	582.1077
	182.1087	582.1087
	182.1091	582.1091
	182.1095	582.1095
	182.1099	582.1099
	182.1125	582.1125
	182.1127	582.1127
	182.1129	582.1129
	182.1131	582.1131
	182.1135	582.1135

See footnotes at end of table.

Old section	New human section	New animal section [1]
121.101(d)	182.1137	582.1137
	182.1139	582.1139
	182.1141	582.1141
	182.1143	582.1143
	182.1155	582.1155
	182.1165	582.1165
	182.1180	NA
	182.1191	582.1191
	182.1193	582.1193
	182.1195	582.1195
	182.1199	582.1199
	182.1205	582.1205
	182.1207	582.1207
	182.1210	582.1210
	182.1217	582.1217
	182.1235	582.1235
	182.1240	582.1240
	182.1275	582.1275
	182.1295	NA
	182.1320	582.1320
	182.1324	582.1324
	182.1355	582.1355
	182.1366	582.1366
	182.1400	582.1400
	182.1425	582.1425
	182.1428	582.1428
	182.1431	582.1431
	182.1440	NA
	182.1480	582.1480
	182.1500	582.1500
	182.1516	582.1516
	182.1540	582.1540
	182.1545	NA
	182.1585	582.1585
	182.1613	582.1613
	182.1619	582.1619
	182.1625	582.1625
	182.1631	582.1631
	182.1643	582.1643
	182.1655	582.1655
	182.1666	582.1666
	182.1685	582.1685
	182.1711	582.1711
	182.1721	582.1721
	182.1736	582.1736
	182.1742	582.1742
	182.1745	582.1745
	182.1748	582.1748
	182.1751	582.1751
	182.1763	582.1763
	182.1775	582.1775
	182.1778	582.1778
	182.1781	582.1781
	182.1792	582.1792
	182.1804	582.1804
	182.1810	582.1810
	182.1901	582.1901
	182.1911	NA
	182.1973	582.1973
	182.1975	582.1975
	182.1978	582.1978
	182.2122	582.2122
	182.2227	582.2227
	182.2437	582.2437
	182.2727	582.2727
	182.2729	582.2729
	182.2906	582.2906
	182.3013	582.3013
	[2] NA	582.3021
	182.3025	NA
	182.3041	582.3041
	182.3081	582.3081
	182.3089	582.3089
	182.3109	582.3109
	182.3149	582.3149
	182.3169	582.3169
	182.3173	582.3173
	182.3189	582.3189
	182.3221	582.3221
	182.3225	582.3225
	182.3280	582.3280
	182.3336	582.3336
	[2] NA	582.3490
	182.3616	582.3616
	182.3637	582.3637
	182.3640	582.3640
	[2] NA	582.3660
	182.3670	582.3670
	182.3731	582.3731
	[2] NA	582.3733
	182.3739	582.3739
	182.3766	582.3766
	182.3784	582.3784
	182.3795	582.3795
	182.3798	582.3798
	182.3845	582.3845
	182.3862	582.3862
	182.3890	582.3890
	182.4029	NA
	182.4037	NA
	182.4053	NA
	182.4101	582.4101
	182.4105	NA
	182.4505	582.4505
	182.4521	582.4521
121.101(d)	182.4560	NA
	182.4666	582.4666
	182.5013	582.5013
	182.5017	582.5017
	182.5049	582.5049
	182.5065	582.5065
	182.5118	582.5118
	182.5145	582.5145
	182.5159	582.5159
	182.5191	582.5191
	182.5195	582.5195
	182.5201	582.5201
	182.5210	582.5210
	182.5212	582.5212
	182.5217	582.5217
	182.5223	582.5223
	182.5230	528.5230
	182.5245	582.5245
	182.5250	582.5250
	182.5252	582.5252
	182.5260	582.5260
	182.5265	NA
	[2] NA	582.5271
	182.5273	582.5273
	182.5301	582.5301
	182.5304	582.5304
	182.5306	582.5306
	182.5308	582.5308
	182.5311	582.5311
	182.5315	582.5315
	182.5361	582.5361
	182.5370	582.5370
	182.5375	582.5375
	182.5381	582.5381
	182.5406	582.5406
	182.5411	582.5411
	182.5431	582.5431
	182.5434	582.5434
	182.5443	582.5443
	182.5446	582.5446
	182.5449	582.5449
	182.5452	582.5452
	182.5455	582.5455
	182.5458	582.5458
	182.5461	582.5461
	182.5464	582.5464
	182.5470	582.5470
	182.5475	582.5475
	182.5477	582.5477
	182.5530	582.5530
	182.5535	582.5535
	182.5580	582.5580
	182.5590	582.5590
	182.5622	582.5622
	182.5628	582.5628
	182.5634	582.5634
	[2] NA	582.5650
	182.5676	582.5676
	182.5695	582.5695
	182.5697	582.5697
	182.5701	582.5701
	182.5772	582.5772
	182.5778	582.5778
	182.5835	582.5835
	182.5875	582.5875
	182.5878	582.5878
	182.5881	582.5881
	182.5890	582.5890
	182.5892	582.5892
	182.5915	582.5915
	182.5920	582.5920
	182.5925	582.5925
	182.5930	582.5930
	182.5933	582.5933
	182.5936	582.5936
	182.5945	582.5945
	182.5950	582.5950
	182.5953	582.5953
	182.5985	582.5985
	182.5988	582.5988
	182.5991	582.5991
	182.5994	582.5994
	182.5997	582.5997
	182.6033	582.6033
	182.6085	582.6085
	182.6099	582.6099
	182.6185	582.6185
	182.6193	582.6193
	182.6195	582.6195
	182.6197	582.6197
	182.6199	582.6199
	182.6203	582.6203
	182.6215	582.6215
	182.6219	582.6219
	182.6285	582.6285
	182.6290	582.6290
	182.6386	582.6386
	182.6611	582.6511
	182.6625	582.6625
	182.6751	582.6751
	182.6754	582.6754
	182.6757	582.6757
	182.6760	582.6760
	182.6769	582.6769
121.101(d)	182.6778	582.6778
	182.6787	582.6787
	182.6789	582.6789
	182.6801	582.6801
	182.6804	582.6804
	182.6807	582.6807
	182.6810	582.6810
	182.6851	582.6851
	182.7115	582.7115
	182.7133	582.7133
	182.7187	582.7187
	182.7255	582.7255
	[2] NA	582.7330
	[2] NA	582.7333
	[2] NA	582.7339
	[2] NA	582.7343
	[2] NA	582.7349
	[2] NA	582.7351
	182.7610	582.7610
	182.7724	582.7724
121.101(e)(1)	182.10	582.10
121.101(e)(2)	182.20	582.20
121.101(e)(3)	182.30	582.30
121.101(e)(4)	182.40	582.40
121.101(e)(5)	182.50	582.50
121.101(f)	NA	582.80
121.101(g)	182.60	582.60
121.101(h)	182.90	NA
121.101(i)	182.70	NA
121.102	182.99	582.99
121.104 except (g)	184.1	NA
121.104(g)(1)	184.1490	NA
121.104(g)(2)	184.1660	NA
121.104(g)(4)	184.1835	NA
121.104(g)(5)	184.1343	NA
121.104(g)(6)	184.1021	NA
121.104(g)(7)	184.1733	NA
121.104(g)(8)	184.1317	NA
121.104(g)(13)	184.1282	NA
121.104(g)(17)	184.1333	NA
121.104(g)(18)	184.1351	NA
121.104(g)(19)	184.1330	NA
121.104(g)(20)	184.1349	NA
121.104(g)(21)	184.1699	NA
121.104(g)(22)	184.1271	NA
121.104(g)(23)	184.1272	NA
121.104(g)(24)	184.1293	NA
121.104(g)(25)	184.1983	NA
121.104(g)(26)	184.1650	NA
121.104(g)(27)	184.1339	NA
121.105 (except (f))	186.1	NA
121.105(f)(1)	186.1343	NA
121.105(f)(2)	186.1339	NA
121.105(f)(3)	186.1673	NA
121.105(f)(4)	186.1330	NA
121.106 except (d) and (e).	189.1	NA
121.106(d)(1)	189.110	NA
121.106(d)(2)	189.145	NA
121.106(d)(3)	189.175	NA
121.106(d)(4)	189.130	NA
121.106(d)(5)	189.135	NA
121.106(d)(6)	189.180	NA
121.106(d)(7)	189.155	NA
121.106(d)(8)	189.190	NA
121.106(d)(9)	189.120	NA
121.106(d)(10)	189.165	NA
121.106(d)(11)	189.140	NA
121.106(e)(1)	189.220	NA
121.106(e)(2)	189.280	NA
121.106(e)(3)	189.250	NA
121.201	NA	573.400
121.202	NA	573.380
121.203	NA	573.820
121.206	NA	573.500
121.209	NA	573.180
121.219	NA	573.480
121.222	NA	573.1000
121.223	NA	573.700
121.224	NA	573.640
121.229	NA	572.940
121.230	NA	573.420
121.231	NA	573.300
121.234	NA	573.600
121.235	NA	573.860
121.236	NA	573.840
121.239	NA	573.780
121.242	NA	573.660
121.246	NA	573.680
121.247	NA	573.580
121.250	NA	573.260
121.261	NA	573.720
121.265	NA	573.320
121.271	NA	573.360
121.272	NA	573.960
121.273	NA	573.900
121.275	NA	573.520
121.277	NA	573.740
121.282	NA	573.560
121.283	NA	573.980
121.284	NA	573.1020
121.285	NA	573.160
121.286	NA	573.620
121.288	NA	573.120
121.295	NA	573.760

See footnotes at end of table.

Old section	New human section	New animal section [1]
121.298	NA	573.440
121.301	NA	573.540
121.302	NA	573.200
121.306	NA	573.280
121.307	NA	573.880
121.313	NA	573.240
121.319	NA	573.140
121.320	NA	573.800
121.322	NA	573.340
121.325	NA	573.920
121.328	NA	573.220
121.329	NA	573.460
121.1000	172.5	NA
121.1001	172.140	NA
121.1002	172.320	NA
121.1004	172.852	NA
121.1008	172.838	NA
121.1009	172.840	NA
121.1010	172.725	NA
121.1012	172.822	NA
121.1015	172.858	NA
121.1016	172.818	NA
121.1017	172.120	NA
121.1018	172.828	NA
121.1019	172.894	NA
121.1021	172.874	NA
121.1023	172.802	NA
121.1027	172.814	NA
121.1028	172.876	NA
121.1029	172.842	NA
121.1030	172.836	NA
121.1031	172.892	NA
121.1032	172.460	NA
121.1034	172.115	NA
121.1035	172.110	NA
121.1036	172.832	NA
121.1037	172.330	NA
121.1039	173.255	NA
121.1040	173.220	NA
121.1041	173.290	NA
121.1042	173.210	NA
121.1043	173.240	NA
121.1044	173.250	NA
121.1045	173.270	NA
121.1047	172.844	NA
121.1048	172.848	NA
121.1050	172.215	NA
121.1056	172.135	NA
121.1058	172.480	NA
121.1059	172.615	NA
121.1060	172.350	NA
121.1063	172.170	NA
121.1064	172.175	NA
121.1065	173.360	NA
121.1066	172.620	NA
121.1067	172.626	NA
121.1068	172.655	NA
121.1069	172.660	NA
121.1070	172.860	NA
121.1071	172.863	NA
121.1073	172.375	NA
121.1077	172.280	NA
121.1080	172.755	NA
121.1081	172.575	NA
121.1082	172.560	NA
121.1084	172.735	NA
121.1085	172.806	NA
121.1086	172.585	NA
121.1087	172.868	NA
121.1088	173.310	NA
121.1089	172.130	NA
121.1090	172.535	NA
121.1091	173.315	NA
121.1092	173.5	NA
121.1095	172.315	NA
121.1097	172.580	NA
121.1098	172.890	NA
121.1099	173.340	NA
121.1100	172.370	NA
121.1101	173.275	NA
121.1102	172.715	NA
121.1105	172.235	NA
121.1109	172.530	NA
121.1110	173.50	NA
121.1111	172.866	NA
121.1112	172.872	NA
121.1113	172.856	NA
121.1114	172.395	NA
121.1116	172.190	NA
121.1119	172.255	NA
121.1120	172.854	NA
121.1122	172.850	NA
121.1123	172.335	NA
121.1125	172.896	NA
121.1130	172.350	NA
121.1132	172.160	NA
121.1134	172.345	NA
121.1135	172.410	NA
121.1136	172.775	NA
121.1137	172.810	NA
121.1139	173.55	NA
121.1141	172.310	NA
121.1142	172.260	NA
121.1146	172.878	NA
121.1148	173.25	NA
121.1149	172.365	NA
121.1151	172.816	NA
121.1154	172.882	NA
121.1155	173.320	NA
121.1156	172.886	NA
121.1160	172.870	NA
121.1161	172.770	NA
121.1162	172.720	NA
121.1163	172.510	NA
121.1164	172.515	NA
121.1165	173.130	NA
121.1166	172.880	NA
121.1170	173.135	NA
121.1171	173.385	NA
121.1174	172.610	NA
121.1176	173.220	NA
121.1179	172.210	NA
121.1180	173.20	NA
121.1181	173.345	NA
121.1182	172.884	NA
121.1183	172.826	NA
121.1185	172.820	NA
121.1186	172.145	NA
121.1190	172.430	NA
121.1192	173.10	NA
121.1193	172.623	NA
121.1194	172.730	NA
121.1195	172.830	NA
121.1197	172.765	NA
121.1198	172.824	NA
121.1199	173.150	NA
121.1202	172.385	NA
121.1203	172.250	NA
121.1208	172.150	NA
121.1209	173.355	NA
121.1211	172.846	NA
121.1213	172.180	NA
121.1219	172.230	NA
121.1221	172.834	NA
121.1224	172.695	NA
121.1225	172.710	NA
121.1228	172.275	NA
121.1229	172.520	NA
121.1230	172.177	NA
121.1233	173.120	NA
121.1235	172.808	NA
121.1237	172.862	NA
121.1238	172.864	NA
121.1239	172.888	NA
121.1244	172.185	NA
121.1246	173.40	NA
121.1250	172.590	NA
121.1255	173.160	NA
121.1257	172.812	NA
121.1258	172.804	NA
121.1259	173.165	NA
121.1260	173.145	NA
121.1262	172.898	NA
121.1263	172.325	NA
121.1265	173.110	NA
121.1266	172.225	NA
121.1267	173.280	NA
121.1268	172.712	NA
121.2000	181.1	NA
121.2005 (introductory offer)	181.22	NA
121.2005(a)	181.24	NA
121.2005(b)	181.23	NA
121.2005(c)	181.25	NA
121.2005(d)	181.26	NA
121.2005(e)	181.27	NA
121.2005(f)	181.28	NA
121.2005(g)	181.29	NA
121.2005(h)	181.30	NA
121.2010	181.32	NA
121.2500	174.1	NA
121.2501	177.1520	NA
121.2502	177.1500	NA
121.2503	178.3930	NA
121.2505	176.300	NA
121.2506	178.3520	NA
121.2507	177.1200	NA
121.2508	178.2550	NA
121.2509	178.3860	NA
121.2510	177.1640	NA
121.2511	178.3740	NA
121.2512	176.110	NA
121.2513	178.3750	NA
121.2514	175.300	NA
121.2515	176.150	NA
121.2516	176.320	NA
121.2517	177.1620	NA
121.2518	176.160	NA
121.2519	176.210	NA
121.2520	175.105	NA
121.2521	177.1980	NA
121.2522	177.1680	NA
121.2523	177.1380	NA
121.2524	177.1630	NA
121.2525	175.210	NA
121.2526	176.170	NA
121.2527	178.3130	NA
121.2528	177.1340	NA
121.2529	176.230	NA
121.2530	178.3850	NA
121.2531	178.3910	NA
121.2532	177.1610	NA
121.2533	177.1240	NA
121.2534	178.3120	NA
121.2535	177.2800	NA
121.2536	177.2260	NA
121.2537	176.130	NA
121.2538	176.120	NA
121.2539	176.350	NA
121.2540	175.350	NA
121.2541	178.3400	NA
121.2543	179.45	NA
121.2544	178.3950	NA
121.2545	177.1850	NA
121.2546	176.260	NA
121.2547	178.1010	NA
121.2548	175.390	NA
121.2549	177.1460	NA
121.2550	177.1210	NA
121.2551	178.3300	NA
121.2552	178.3500	NA
121.2553	178.3570	NA
121.2554	177.1330	NA
121.2555	177.1550	NA
121.2556	178.3800	NA
121.2557	176.200	NA
121.2558	178.3530	NA
121.2559	175.380	NA
121.2561	176.250	NA
121.2561	178.3450	NA
121.2562	177.2600	NA
121.2563	178.3970	NA
121.2564	177.1310	NA
121.2565	178.3290	NA
121.2566	178.2010	NA
121.2567	177.1400	NA
121.2569	175.320	NA
121.2570	177.1350	NA
121.2571	176.180	NA
121. 2572	177. 1650	NA
121. 2573	178. 3730	NA
121. 2574	177. 1580	NA
121. 2575	175. 250	NA
121. 2576	177. 2420	NA
121. 2577	175. 125	NA
121. 2578	175. 230	NA
121. 2579	177. 1440	NA
121. 2580	177. 1600	NA
121. 2581	177. 2430	NA
121. 2582	177. 1330	NA
121. 2583	178. 3010	NA
121. 2584	177. 2710	NA
121. 2585	177. 2280	NA
121. 2586	178. 3710	NA
121. 2587	177. 2410	NA
121. 2588	178. 3700	NA
121. 2589	178. 3620	NA
121. 2590	177. 1420	NA
121. 2591	177. 1010	NA
121. 2592	178. 3870	NA
121. 2593	177. 2510	NA
121. 2594	178. 3650	NA
121. 2595	177. 1900	NA
121. 2596	178. 3900	NA
121. 2597	178. 3790	NA
121. 2598	177. 1670	NA
121. 2599	175. 360	NA
121. 2600	175. 365	NA
121. 2601	175. 260	NA
121. 2602	178. 3950	NA
121. 2603	177. 2460	NA
121. 2604	178. 3600	NA
121. 2605	178. 3770	NA
121. 2606	178. 3940	NA
121. 2607	178. 3760	NA
121. 2608	177. 1970	NA
121. 2609	177. 1950	NA
121. 2610	177. 1430	NA
121. 2611	177. 1830	NA
121. 2612	175. 270	NA
121. 2613	177. 2500	NA
121. 2614	177. 1480	NA
121. 2615	178. 3610	NA
121. 2616	178. 3480	NA
121. 2617	177. 1570	NA
121. 2618	178. 3720	NA
121. 2619	177. 1380	NA
121. 2620	178. 3280	NA
121. 2621	177. 2490	NA
121. 2622	177. 1810	NA
121. 2623	177. 1960	NA
121. 2624	178. 3550	NA
121. 2625	177. 1060	NA
121. 2626	177. 1820	NA
121. 2627	177. 1030	NA
121. 2628	177. 2450	NA
121. 2629	177. 1040	NA
121. 2630	178. 3780	NA
121. 2631	177. 2220	NA
121. 2632	177. 1590	NA
121. 2633	177. 1020	NA
121. 2634	177. 2010	NA
121. 2635	177. 1660	NA
121. 2636	177. 2210	NA
121. 2637	177. 2470	NA

See footnotes at end of table.

Old section	New human section	New animal section [1]
121.2638	177.2480	NA
121.3001	179.21	NA
121.3003	179.22	NA
121.3006	179.39	NA
121.3007	179.24	NA
121.3008	179.30	NA
121.4000	180.1	NA
121.4001	180.37	NA
121.4004	180.30	NA
121.4005	180.25	NA
121.4010	180.22	NA
122.1	109.3	509.3
122.10	109.30	509.30
125.1	105.3	NA
125.2	105.60	NA
125.3	105.77	NA
125.5	105.65	NA
125.6	105.67	NA
125.7	105.79	NA
125.8	105.62	NA
125.9	105.69	NA
128.1	110.3	NA
128.2	110.1	NA
128.3	110.20	NA
128.4	110.40	NA
128.5	110.35	NA
128.6	110.37	NA
128.7	110.80	NA
128.8	110.10	NA
128.9	110.19	NA
128.10	110.90	NA
128a.1	122.3	NA
128a.2	122.1	NA
128a.3	122.20	NA
128a.4	122.40	NA
128a.5	122.35	NA
128a.6	122.37	NA
128a.7	122.80	NA
128a.401	123.3	NA
128a.402	123.1	NA
128a.403	123.20	NA
128a.404	123.40	NA
128a.405	123.35	NA
128a.406	123.37	NA
128a.407	123.80	NA
128b.1	113.3	507.3
128b.2	113.1	507.1
128b.3	113.81	507.81
128b.4	113.83	507.83
128b.5	113.87	507.87
128b.6	113.40	507.40
128b.7	113.60	507.60
128b.8	113.100	507.100
128b.9	113.89	507.89
128b.10	113.10	507.10
128c.1	118.3	NA
128c.2	118.1	NA
128c.3	118.20	NA
128c.4	118.40	NA
128c.5	118.35	NA
128c.6	118.37	NA
128c.7	118.80	NA
128c.8	118.100	NA
128d.1	129.3	NA
128d.2	129.1	NA
128d.3	129.20	NA
128d.4	129.40	NA
128d.5	129.35	NA
128d.6	129.37	NA
128d.7	129.80	NA

[1] The text of the animal food regulations listed in this columnare set forth in the fourteenth recodification document published in the FEDERAL REGISTER of Sept. 10, 1976 (41 FR 38618).

[2] § 570.3 does not include pars. (n) and (o) of former § 121.1.

[3] The procedure for listing substances when affirmed as GRAS is to eliminate them from listing in Part 182 (formerly § 121.101(d)). For substances affirmed as GRAS in human food, see Parts 184 and/or 186. For all GRAS substances in animal food see Part 582 (published in the Federal Register of September 10, 1976 (41 FR 38618)).

The changes being made are nonsubstantive in nature and for this reason notice and public procedure are not prerequisites to this promulgation. For the convenience of the user, the entire text of reorganized Subchapter B, except Part 193 under the jurisdiction of the Environmental Protection Agency, is set forth below.

Dated: March 4, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

SUBCHAPTER B—FOODS FOR HUMAN CONSUMPTION

Part:

100 General.
101 Food labeling.
102 Common or usual name for nonstandardized foods.
103 Quality standards for foods with no identity standards.
104 Nutritional quality guidelines for foods.
105 Foods for special dietary use.
108 Emergency permit control.
109 Unavoidable contaminants in food and food-packaging material.
110 Current good manufacturing practice in manufacturing, processing, packing, or holding human food.
113 Thermally processed low-acid foods packaged in hermetically sealed containers.
118 Cacao products and confectionery.
122 Smoked and smoke-flavored fish.
123 Frozen raw breaded shrimp.
129 Processing and bottling of bottled drinking water.
130 Food standards: general.
131 Milk and cream.
133 Cheeses and related cheese products.
135 Frozen desserts.
136 Bakery products.
137 Cereal flours and related products.
139 Macaroni and noodle products.
145 Canned fruits.
146 Canned fruit juices.
150 Fruit butters, jellies, preserves, and related products.
152 Fruit pies.
155 Canned vegetables.
156 Vegetable juices.
158 Frozen vegetables.
160 Eggs and egg products.
161 Fish and shellfish.
163 Cacao products.
164 Tree nut and peanut products.
165 Nonalcoholic beverages.
166 Margarine.
168 Sweeteners and table sirups.
169 Food dressings and flavorings.
170 Food additives.
171 Food additive petitions.
172 Food additives permitted for direct addition to food for human consumption.
173 Secondary direct food additives permitted in food for human consumption.
174 Indirect food additives, general.
175 Indirect food additives—adhesive coatings and components.
176 Indirect food additives—paper and paperboard components.
177 Indirect food additives—polymers.
178 Indirect food additives—adjuvants, production aids, and sanitizers.
179 Irradiation in the production, processing and handling of food.
180 Food additives permitted in food on an interim basis or in contact with food pending additional study.
181 Prior-sanctioned food ingredients.
182 Substances generally recognized as safe.
184 Direct food substances affirmed as generally recognized as safe.
186 Indirect food substances affirmed as generally recognized as safe.
189 Substances prohibited from use in human food.
193 [1] Tolerances for pesticides in food administered by the Environmental Protection Agency.
197 Seafood inspection program.

[1] Full text of this part, transferred from former Part 121, was set out under Part 123 in the tenth recodification document published in the FEDERAL REGISTER of March 28, 1975 (40 FR 14156). Part 123 was subsequently transferred to Part 193 by publication in the FEDERAL REGISTER of June 28, 1976 (41 FR 26565).

PART 100—GENERAL

Subparts A–F—[Reserved]

Subpart G—Specific Administrative Rulings and Decisions

Sec.
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100.160 Tolerances for moldy and insect-infected cocoa beans.

AUTHORITY: Sec. 701, 52 Stat. 1055–1056 as amended (21 U.S.C. 371) unless otherwise noted.

Subparts A–F [Reserved]

Subpart G—Specific Administrative Rulings and Decisions

§ 100.120 Artificially red-dyed yellow varieties of sweet potatoes.

(a) It has been the practice of some growers, packers, and distributors of yellow varieties of sweet potatoes to artificially color the skins of such potatoes with a red dye. Surveys made by the Food and Drug Administration and letters received by the Administration from consumers reveal that this practice can deceive those persons who prefer the naturally red varieties of sweet potatoes. Also, representatives of the red sweet potato industry have alleged that some consumers refuse to purchase any red sweet potatoes since they cannot distinguish between the naturally red ones and those artificially colored with red dye.

(b) The Food and Drug Administration concludes, therefore, that yellow varieties of sweet potatoes artificially colored with a red dye are adulterated within the meaning of section 402(b) of the Federal Food, Drug, and Cosmetic Act.

(c) The Food and Drug Administration will consider appropriate regulatory action regarding such adulterated sweet potatoes shipped in interstate commerce if the act of adulterating the potatoes occurs after 90 days following the date of publication of this statement of policy in the FEDERAL REGISTER.

(Sec. 402(b), 52 Stat. 1046–1047 (21 U.S.C. 342 (b)).)

§ 100.130 Combinations of nutritive and nonnutritive sweeteners in "diet beverages."

As a result of the removal of cyclamic acid and its salts from the list of substances generally recognized as safe (Part 182 of this chapter) by an order published in the FEDERAL REGISTER of October 21, 1969 (34 FR 17063), the Commissioner of Food and Drugs has received inquiries as to the proper composition and labeling, from the standpoint of application of the Federal Food, Drug, and Cosmetic Act, of so-called "diet beverages" that will be made from

mixtures of nutritive sweeteners and saccharin or its salts. The Commissioner concludes that:

(a) Any "diet beverage" or diet beverage base made with combinations of nutritive and nonnutritive sweeteners must be so formulated that each ingredient is one which is generally recognized as safe and is not a food additive as defined in section 201(s) or a color additive as defined in section 201(t) of the act, or if it is a food additive or a color additive as so defined, is used in accordance with a regulation established pursuant to section 409 or 706 of the act.

(b) The product is to be so formulated that its caloric value is at least 50 percent less than the caloric value of the comparable product made without artificial sweeteners. In no case shall the beverage provide more than 6 calories per fluid ounce.

(c) If it is to be marketed under a name heretofore used on a product represented to have no, or only a few, calories per serving, the name shall be modified by the word "new" for at least 1 year following the time such product is introduced in a given market.

(d) (1) The label must bear a complete statement of ingredients except that spices, flavorings, and colorings may be designated as such without naming each.

(2) The label must bear a statement of the caloric content per fluid ounce, the carbohydrate content per fluid ounce, a statement of the percentage of saccharin or saccharin salt used, and the statement "Contains ------ mg saccharin (or saccharin salt, as the case may be) per ounce, a nonnutritive artificial sweetener".

(3) To further avoid injury through inadvertent use by diabetics in the belief that the product does not contain carbohydrates, the label of a beverage containing sugar(s) must bear the statement "Contains sugar(s); not for use by diabetics without advice of a physician."

(4) To avoid confusion by diabetics, the label of a beverage containing sorbitol, mannitol, or other hexitol, must bear the statement "Contains carbohydrates, not for use by diabetics without advice of a physician". To further avoid confusion of these beverages with those sweetened solely with nonnutritive artificial sweeteners which have been marketed in containers bearing prominent statements such as "sugar free", "sugarless", or "no sugar", the labels of beverages containing hexitols must not bear these or similar statements.

(e) Bottlers of diet drinks have on hand large stocks of returnable lithographed bottles bearing statements indicating that the beverages contain cyclamates and/or declarations such as "sugar free", "less than 1 calorie per bottle", or "less than 2 calories per bottle" which bottles were formerly used for artificially sweetened beverages containing cyclamates. The Food and Drug Administration will not object to continued use of these bottles under the following conditions:

(1) The bottles when filled with beverages made with combinations of nutritive and nonnutritive sweeteners may be marketed only:

(i) In multiunit cartons labeled prominently on each principal display panel with the information set forth in paragraphs (c) and (d) of this section and with a prominent, forthright notice that any information on bottles which is contrary to that on the cartons should be disregarded because it is incorrect. To assure adequate prominence and conspicuousness, the following statements should stand out in marked contrast with other labeling: The statement of caloric content and carbohydrate content per fluid ounce, the statement required by paragraph (d) (3) or (4) of this section as applicable, and the notice to disregard any information on bottles which is contrary to that on the cartons. These statements may be made to stand out by means such as setting them forth in boxes, printing in bold capitals on lines separated from other printed labeling, using colors that contrast with those used for other label statements, or other similar means.

(ii) In vending machines bearing durable labeling which includes all of the information required to appear on cartons set forth with the same degree of prominence.

(2) In addition, the bottles must bear caps labeled prominently with the words "Contains Sugar" or "Contains Carbohydrates", and accurate statements of the caloric content and carbohydrate content per fluid ounce.

(Secs. 201(s), 403, 409(d), 52 Stat. 1047–1048, as amended, 72 Stat. 1784 as amended, 1787 (21 U.S.C. 321(s), 343, 348).)

§ 100.135 Disposition of incubator reject eggs.

(a) Investigations by the Food and Drug Administration and a number of State regulatory agencies have revealed that incubator reject eggs, removed as infertile or otherwise unhatchable during hatching operations, are being diverted for human food use. Such eggs are regarded as adulterated within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(3)) because they are unfit for food.

(b) The introduction or delivery for introduction into interstate commerce of adulterated eggs is prohibited under section 301(a) of the aforesaid act (21 U.S.C. 331(a)) unless they have been broken, crushed, or smashed and then denatured with kerosene, creolin, or other suitable denaturant to preclude their diversion to human food channels.

(Secs. 301, 402, 52 Stat. 1042, 1046 (21 U.S.C. 331, 342.)

§ 100.140 Label declaration of salt in frozen vegetables.

(a) In a number of diseases or disease conditions it is important to restrict the intake of sodium. Sodium occurs in all natural foods, but added salt makes the most important contribution to the total sodium intake in the diet. Most fresh vegetables are of low sodium content and consumers generally regard frozen vegetables as being free of added salt and suitable for use in low-sodium diets. While salt may not be added directly as a seasoning ingredient during the processing of frozen vegetables, the use of salt brine in quality separation of such vegetables as peas and lima beans preparatory to freezing may contribute substantial amounts of salt to the finished article. The failure of the labels of frozen vegetables to declare the presence of salt has been the basis of complaints to the Food and Drug Administration.

(b) Section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act requires the label of a fabricated food to bear the common or usual name of each ingredient present. The Department of Health, Education, and Welfare regards any frozen vegetable containing salt, added directly or indirectly, as misbranded in violation of section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act unless its label names salt as an ingredient.

§ 100.145 Notice to packers of comminuted tomato products.

(a) It has long been known that tomato rot may be caused by one or more of the following: Fungus diseases, bacterial diseases, virus diseases, and certain nonparasitic diseases. Only the fungus rots are characterized by the presence of mold filaments. Mold counts on comminuted tomato products are not increased by incorporating within the product tomato rot caused by bacteria, virus, or nonparasitic factors. Although high mold counts on these products reveal that large amounts of rotten material are present, low mold counts do not necessarily demonstrate absence of the type of rot caused by the tomato diseases that are not characterized by mold filaments.

(b) Inspections of canneries engaged in the packing of comminuted tomato products show that most packers effectively trim, sort out, and discard rotten tomatoes from the raw stock. Some packers, however, do not properly eliminate rotten tomato material, and a few packers deliberately use rotten tomatoes in these foods, provided the mold count remains low. Some packers, on occasion, have mixed tomato products having a high mold count with tomato products containing little or no mold, so as to produce a blend with a low mold count.

(c) Packers of comminuted tomato products who rely upon the mold count as the sole or primary control procedure, to the neglect of adequate sorting and trimming, may produce products with low mold counts which contain substantial amounts of rot.

(d) It is the purpose of this announcement to advise all canners of tomato products that:

(1) Although high mold count is conclusive evidence of inclusion of substantial amounts of rot, mold count is not the only way of establishing that comminuted tomato products contain decomposed tomato material.

(2) Where factory observations or other evidence reveals that comminuted

tomato products contain rot not caused by mold, such rot, as well as that caused by mold, will be taken into account in applying the provisions of the Federal Food, Drug, and Cosmetic Act against adulteration.

(3) The blending of tomato products adulterated with tomato rot, of whatever kind, with tomato products made from sound tomatoes, or with other sound food, renders the blend adulterated.

§ 100.150 Notice to packers and shippers of shelled peanuts.

(a) Investigations by the Food and Drug Administration have shown that a number of interstate shipments of shelled peanuts in bags holding from approximately 100 to 125 pounds each have failed to bear labeling as required by the terms of the Federal Food, Drug, and Cosmetic Act.

(b) Shelled peanuts in sacks, whether or not shipped in carload lots, should bear the following information required by the law on food in package form:

(1) The name of the product.

(2) An accurate statement of net weight.

(3) The name and place of business of the packer or distributor.

(c) The information required by paragraph (b) of this section should be conspicuously set forth. It may be printed or stenciled on each bag or, if desired, placed on tags which are securely attached to each bag.

(d) The net weight marked on the bags must be the correct net weight of the peanuts at the time they are delivered to the carrier for interstate shipment. The tare weight of the bag should not be included in the weight declaration.

§ 100.155 Salt and iodized salt.

(a) For the purposes of this section, the term "iodized salt" or "iodized table salt" is designated as the name of salt for human food use to which iodide has been added in the form of cuprous iodide or potassium iodide permitted by §§ 182.5265 and 182.5634 of this chapter. In the labeling of such products, all words in the name shall be equal in prominence and type size. The statement "This salt supplies iodide, a necessary nutrient" shall appear on the label immediately following the name and shall be in letters which are not less in height than those required for the declaration of the net quantity of contents as specified in § 101.105 of this chapter.

(b) Salt or table salt for human food use to which iodide has not been added shall bear the statement, "This salt does not supply iodide, a necessary nutrient." This statement shall appear immediately following the name of the food and shall be in letters which are not less in height than those required for the declaration of the net quantity of contents as specified in §101.105 of this chapter.

(c) Salt, table salt, iodized salt, or iodized table salt to which anticaking agents have been added may bear in addition to the ingredient statement designating the anticaking agent(s), a label statement describing the characteristics imparted by such agent(s) (for example, "free flowing"), providing such statement does not appear with greater prominence or in type size larger than the statements which immediately follow the name of the food as required by paragraphs (a) and (b) of this section.

(d) Individual serving-sized packages containing less than ½ ounce and packages containing more than 2½ pounds of a food described in this section shall be exempt from declaration of the statements which paragraphs (a) and (b) of this section require immediately following the name of the food. Such exemption shall not apply to the outer container or wrapper of a multiunit retail package.

(e) All salt, table salt, iodized salt, or iodized table salt in packages intended for retail sale shipped in interstate commerce 18 months after the date of publication of this statement of policy in the FEDERAL REGISTER, shall be labeled as prescribed by this section; and if not so labeled, the Food and Drug Administration will regard them as misbranded within the meaning of section 403 (a) and (f) of the Federal Food, Drug, and Cosmetic Act.

(Secs. 403 (a) and (f), 52 Stat. 1047 (21 U.S.C. 343 (a) and (f)).)

§ 100.160 Tolerances for moldy and insect-infested cocoa beans.

On and after February 22, 1963, shipments of cocoa beans offered for entry into the United States must meet a tolerance of 6 percent total moldy and insect-infested, including insect-damaged, beans, but not more than 4 percent of either moldy or insect-infested, including insect-damaged, beans. This statement of policy supersedes the notice issued August 27, 1931, addressed to shippers, importers, and dealers in cocoa beans and manufacturers of chocolate and cocoa products and the statement of policy issued June 22, 1961, in this section.

(Sec. 402(a)(3), 68 Stat. 511 (21 U.S.C. 342 (a)(3)).

PART 101—FOOD LABELING

Subpart A—General Provisions

Sec.
101.1 Principal display panel of package form food.
101.2 Information panel of package form food.
101.3 Identity labeling of food in packaged form.
101.4 Food; designation of ingredients.
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101.22 Foods; labeling of spices, flavorings, colorings and chemical preservatives.
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101.35 Notice to manufacturers and users of monosodium glutamate and other hydrolyzed vegetable protein products.

Subparts C through E—[Reserved]

Subpart F—Exemptions From Food Labeling Requirements

101.100 Food; exemptions from labeling.
101.103 Petitions requesting exemptions from or special requirements for label declaration of ingredients.
101.105 Declaration of net quantity of contents when exempt.

AUTHORITY: Secs. 4, 6, Pub. L. 89-755, 80 Stat. 1297, 1299, 1300 (15 U.S.C. 1453, 1455); secs. 403, 602, 701, Pub. L. 717, 52 Stat. 1047, 1054, 1055 as amended (21 U.S.C. 343, 362, 371), unless otherwise noted.

Subpart A—General Provisions

§ 101.1 Principal display panel of package form food.

The term "principal display panel" as it applies to food in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring design, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term "area of the principal display panel" means the area of the side or surface that bears the principal display panel, which area shall be:

(a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

(b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference;

(c) In the case of any otherwise shaped container, 40 percent of the total surface of the container: *Provided, however,* That where such container presents an obvious "principal display panel" such as the top of a triangular or circular package of cheese, the area shall consist of the entire top surface. In determining the area of the principal display panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal

display panel shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

§ 101.2 Information panel of package form food.

(a) The term "information panel" as it applies to packaged food means that part of the label immediately contiguous and to the right of the principal display panel as observed by an individual facing the principal display panel with the following exceptions:

(1) If the part of the label immediately contiguous and to the right of the principal display panel is too small to accommodate the necessary information or is otherwise unusable label space, e.g., folded flaps or can ends, the panel immediately contiguous and to the right of this part of the label may be used.

(2) If the package has one or more alternate principal display panels, the information panel is immediately contiguous and to the right of any principal display panel.

(3) If the top of the container is the principal display panel and the package has no alternate principal display panel, the information panel is any panel adjacent to the principal display panel.

(b) All information required to appear on the label of any package of food pursuant to §§ 101.4, 101.5, 101.8, 101.9, 101.17, 101.25 and Part 105 of this chapter shall appear either on the principal display panel or on the information panel, unless otherwise specified by regulations in this chapter.

(c) All information appearing on the principal display panel or the information panel pursuant to this section shall appear prominently and conspicuously, but in no case may the letters and/or numbers be less than one-sixteenth inch in height unless an exemption pursuant to paragraph (f) of this section is established. The requirements for conspicuousness and legibility shall include the specifications of §§ 101.105(h) (1) and (2) and § 101.15.

(1) Packaged foods are exempt from the type size requirements of this paragraph: *Provided*, That:

(i) The package is designed such that it has a surface area that can bear an information panel and/or an alternate principal display panel.

(ii) The area of surface available for labeling on the principal display panel of the package as this term is defined in § 101.1 is less than 10 square inches.

(iii) The label information includes nutrition information and a full list of ingredients in accordance with regulations in this part and the policy expressed in § 101.6.

(iv) The information required by paragraph (b) of this section appears on the principal display panel or information panel label in accordance with the provisions of this paragraph (c) except that the type size is not less than three sixty-fourths inch in height.

(2) Packaged foods are exempt from the type size requirements of this paragraph: *Provided*, That:

(i) The package is designed such that it has a single "obvious principal display panel" as this term is defined in § 101.1 and has no other available surface area for an information panel or alternate principal display panel.

(ii) The area of surface available for labeling on the principal display panel of the package as this term is defined in § 101.1 is less than 12 square inches and bears all labeling appearing on the package.

(iii) The label information includes nutrition information and a full list of ingredients in accordance with regulations in this part and the policy expressed in §101.6.

(iv) The information required by paragraph (b) of this section appears on the single, obvious principal display panel in accordance with the provisions of this paragraph (c) except that the type size is not less than one thirty-second inch in height.

(3) Packaged foods are exempt from the type size requirements of this paragraph: *Provided*, That:

(i) The package is designed such that it has a total surface area available to bear labeling of less than 12 square inches.

(ii) The label information includes nutrition information and a full list of ingredients in accordance with regulations in this part and the policy expressed in § 101.6.

(iii) The information required by paragraph (b) of this section appears on the principal display panel or information panel label in accordance with the provisions of this paragraph (c) except that the type size is not less than one thirty-second inch in height.

(4) (i) Soft drinks packaged in bottles manufactured before October 31, 1975 shall be exempt from the requirements prescribed by this section to the extent that information which is blown, lithographed, or formed onto the surface of the bottle is exempt from the size and placement requirements of this section.

(ii) Soft drinks packaged in bottles shall be exempt from the size and placement requirements prescribed by this section if all of the following conditions are met:

(*a*) If the soft drink is packaged in a bottle bearing a paper, plastic foam jacket or foil label, or is packaged in a nonreusable bottle bearing a label lithographed onto the surface of the bottle, the product shall not be exempt from any requirement of this section other than the exemption created by § 1.1c(a) (5) (ii) of this chapter and the label shall bear all required information in the specified minimum type size, except the label will not be required to bear the information required by § 101.5 if this information appears on the bottle closure in a type size not less than one-sixteenth inch in height.

(*b*) If the soft drink is packaged in a bottle which does not bear a paper, plastic foam jacket or foil label, or is packaged in a reusable bottle bearing a label lithographed onto the surface of the bottle:

(*1*) Neither the bottle nor the closure is required to bear nutrition labeling in compliance with § 101.9, except that any multiunit retail package in which it is contained shall bear nutrition labeling if required by § 101.9; and any vending machine in which it is contained shall bear nutrition labeling if nutrition labeling is not present on the bottle or closure, if required by § 101.9.

(*2*) All other information pursuant to this section shall appear on the top of the bottle closure prominently and conspicuously in letters and/or numbers no less than one thirty-second inch in height, except that if the information required by § 101.5 is placed on the side of the closure in accordance with § 1.1c (a) (5) (ii) of this chapter, such information shall appear in letters and/or numbers no less than one-sixteenth inch in height.

(*3*) Upon the petition of any interested person demonstrating that the bottle closure is too small to accommodate this information, the Commissioner may by regulation establish an alternative method of disseminating such information. Information appearing on the closure shall appear in the following priority:

(*i*) The warning required by § 100.130 of this chapter.

(*ii*) The statement of ingredients.

(*iii*) The name and address of the manufacturer, packer, or distributor.

(*iv*) The statement of identity.

(d) (1) All information required to appear on the principal display panel or on the information panel pursuant to this section shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, any vignettes, design, and other nonmandatory label information shall not be considered. If there is insufficient space for all of this information to appear on a single panel, it may be divided between these two panels except that the information required pursuant to any given section or part shall all appear on the same panel. A food whose label is required to bear the ingredient statement on the principal display panel may bear all other information specified in paragraph (b) of this section on the information panel.

(2) Any of the foods listed in § 1.1c (a) (6) (i) and (7) (i), and §§ 133.128, 133.129, and 133.131 of this chapter, and yogurt and yogurt products, when packaged in a container consisting of a separate lid and body and bearing nutrition labeling pursuant to § 101.9, and the lid is designed as a principal display panel, shall be exempt from the placement requirements of this section in the following respects.

(i) The name and place of business information required by § 101.5 shall not be required on the body of the container if this information appears on the lid in accordance with this section.

(ii) The nutrition information required by § 101.9 shall not be required on the lid if this information appears on the container body in accordance with this section.

(iii) The statement of ingredients required by § 101.4 shall not be required on the lid if this information appears on the container body in accordance with this section. Further, the statement of ingredients is not required on the container body if this information appears on the lid in accordance with this section.

(e) All information appearing on the information panel pursuant to this section shall appear in one place without other intervening material.

(f) If the label of any package of food is too small to accommodate all of the information required by §§ 101.4, 101.5, 101.8, 101.9, 101.17, and 101.25, and Part 105 of this chapter, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, e.g., a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph shall be submitted pursuant to Part 2 of this chapter.

§ 101.3 Identity labeling of food in packaged form.

(a) The principal display panel of a food in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of:

(1) The name now or hereafter specified in or required by any applicable Federal law or regulation; or, in the absence thereof,

(2) The common or usual name of the food; or, in the absence thereof,

(3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

(c) Where a food is marketed in various optional forms (whole, slices, diced, etc.), the particular form shall be considered to be a necessary part of the statement of identity and shall be declared in letters of a type size bearing a reasonable relation to the size of the letters forming the other components of the statement of identity; except that if the optional form is visible through the container or is depicted by an appropriate vignette, the particular form need not be included in the statement. This specification does not affect the required declarations of identity under definitions and standards for foods promulgated pursuant to section 401 of the act.

(d) This statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

(e) Under the provisions of section 403(c) of the Federal Food, Drug, and Cosmetic Act, a food shall be deemed to be misbranded if it is an imitation of another food unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(1) A food shall be deemed to be an imitation and thus subject to the requirements of section 403(c) of the act if it is a substitute for and resembles another food but is nutritionally inferior to that food.

(2) A food that is a substitute for and resembles another food shall not be deemed to be an imitation provided it meets each of the following requirements:

(i) It is not nutritionally inferior to the food for which it substitutes and which it resembles.

(ii) Its label bears a common or usual name that complies with the provisions of § 102.5 of this chapter and that is not false or misleading, or in the absence of an existing common or usual name, an appropriately discriptive term that is not false or misleading. The label may, in addition, bear a fanciful name which is not false or misleading.

(3) A food for which a common or usual name is established by regulation (e.g., in a standard of identity pursuant to section 401 of the act, in a common or usual name regulation pursuant to Part 102 of this chapter, or in a regulation establishing a nutritional quality guideline pursuant to Part 104 of this chapter), and which complies with all of the applicable requirements of such regulation(s), shall not be deemed to be an imitation.

(4) Nutritional inferiority includes: (i) Any reduction in the content of an essential nutrient that is present in a measurable amount, but does not include a reduction in the caloric or fat content provided the food is labeled pursuant to the provisions of § 101.9, and provided the labeling with respect to any reduction in caloric content complies with the provisions applicable to caloric content in Part 105 of this chapter.

(ii) For the purpose of this section, a measurable amount of an essential nutrient in a food shall be considered to be 2 percent or more of the U.S. RDA of protein or any vitamin or mineral listed under § 105.3(b) of this chapter per average or usual serving, or where the food is customarily not consumed directly, per average or usual portion, as established in § 101.9.

(iii) If the Commissioner concludes that a food is a substitute for and resembles another food but is inferior to the food imitated for reasons other than those set forth in this paragraph, he may propose appropriate revisions to this regulation or he may propose a separate regulation governing the particular food.

(f) A label may be required to bear the percentage(s) of a characterizing ingredient(s) or information concerning the presence or absence of an ingredient(s) or the need to add an ingredient(s) as part of the common or usual name of the food pursuant to Subpart B of Part 102 of this chapter.

(Secs. 403, 701(a), 52 Stat. 1047-1048, as amended, 1055 (21 U.S.C. 343, 371(a)).

§ 101.4 Food; designation of ingredients.

(a) Ingredients required to be declared on the label of a food, including foods that comply with standards of identity that require labeling in compliance with this Part 101, except those exempted by § 101.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of § 101.2.

(b) The name of an ingredient shall be a specific name and not a collective (generic) name, except that:

(1) Spices, flavorings, colorings and chemical preservatives shall be declared according to the provisions of § 101.22.

(2) An ingredient which itself contains two or more ingredients and which has an established common or usual name, conforms to a standard established pursuant to the Meat Inspection or Poultry Products Inspection Acts by the U.S. Department of Agriculture, or conforms to a definition and standard of identity established pursuant to section 401 of the Federal Food, Drug, and Cosmetic Act, shall be designated in the statement of ingredients on the label of such food by either of the following alternatives:

(i) By declaring the established common or usual name of the ingredient followed by a parenthetical listing of all ingredients contained therein in descending order of predominance except that, if the ingredient is a food subject to a definition and standard of identity established in this Subchapter B, only the ingredients required to be declared by the definition and standard of identity need be listed; or

(ii) By incorporating into the statement of ingredients in descending order of predominance in the finished food, the common or usual name of every component of the ingredient without listing the ingredient itself.

(3) Skim milk, concentrated skim milk, reconstituted skim milk, and nonfat dry milk may be declared as "skim milk" or "nonfat milk".

(4) Milk, concentrated milk, reconstituted milk, and dry whole milk may be declared as "milk".

(5) Bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, e.g., "made from cultured skim milk or cultured buttermilk".

(6) Sweetcream buttermilk, concentrated sweetcream buttermilk, reconstituted sweetcream buttermilk, and dried sweetcream buttermilk may be declared as "buttermilk".

(7) Whey, concentrated whey, reconstituted whey, and dried whey may be declared as "whey".

(8) Cream, reconstituted cream, dried cream, and plastic cream (sometimes known as concentrated milk fat) may be declared as "cream".

(9) Butteroil and anhydrous butterfat may be declared as "butterfat".

(10) Dried whole eggs, frozen whole eggs, and liquid whole eggs may be declared as "eggs".

(11) Dried egg whites, frozen egg whites, and liquid egg whites may be declared as "egg whites".

(12) Dried egg yolks, frozen egg yolks, and liquid egg yolks may be declared as "egg yolks".

(13) [Reserved]

(14) Each individual fat and/or oil ingredient of a food intended for human consumption shall be declared by its specific common or usual name (e.g., "beef fat", "cottonseed oil") in its order of predominance in the food except that blends of fats and/or oils may be designated in their order of predominance in the food as "____ shortening" or "blend of ____ oils", the blank to be filled in with the word "vegetable", "animal", "marine", with or without the terms "fat" or "oils", or combination of these, whichever is applicable if, immediately following the term, the common or usual name of each individual vegetable, animal, or marine fat or oil is given in parentheses, e.g., "vegetable oil shortening (soybean and cottonseed oil)". For products that are blends of fats and/or oils and for foods in which fats and/or oils constitute the predominant ingredient, i.e., in which the combined weight of all fat and/or oil ingredients equals or exceeds the weight of the most predominant ingredient that is not a fat or oil, the listing of the common or usual names of such fats and/or oils in parentheses shall be in descending order of predominance. In all other foods in which a blend of fats and/or oils is used as an ingredient, the listing of the common or usual names in parentheses need not be in descending order of predominance if the manufacturer, because of the use of varying mixtures, is unable to adhere to a constant pattern of fats and/or oils in the product. If the fat or oil is completely hydrogenated, the name shall include the term "saturated", or if partially hydrogenated, the name shall include the term "partially saturated". Fat and/or oil ingredients not present in the product may be listed if they may sometimes be used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as "or", "and/or", "contains one or more of the following:", e.g., "vegetable oil shortening (contains one or more of the following: cottonseed oil, palm oil, soybean oil)". No fat or oil ingredient shall be listed unless actually present if the fats and/or oils constitute the predominant ingredient of the product, as defined in this paragraph (b)(14).

(15) When all the ingredients of a wheat flour are declared in an ingredient statement, the principal ingredient of the flour shall be declared by the name(s) specified in §§ 137.105, 137.200, 137.220 and 137.225 of this chapter, i.e., the first ingredient designated in the ingredient list of flour, or bromated flour, or enriched flour, or self-rising flour is "flour", "white flour", "wheat flour", or "plain flour"; the first ingredient designated in the ingredient list of durum flour is "durum flour"; the first ingredient designated in the ingredient list of whole wheat flour, or bromated whole wheat flour is "whole wheat flour", "graham flour", or "entire wheat flour"; and the first ingredient designated in the ingredient list of whole durum wheat flour is "whole durum wheat flour".

(c) When water is added to reconstitute, completely or partially, an ingredient permitted by paragraph (b) of this section to be declared by a class name, the position of the ingredient class name in the ingredient statement shall be determined by the weight of the unreconstituted ingredient plus the weight of the quantity of water added to reconstitute that ingredient, up to the amount of water needed to reconstitute the ingredient to single strength. Any water added in excess of the amount of water needed to reconstitute the ingredient to single strength shall be declared as "water" in the ingredient statement.

§ 101.5 Food; name and place of business of manufacturer, packer, or distributor.

(a) The label of a food in packaged form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.

(b) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, only by the actual corporate name, which may be preceded or followed by the name of the particular division of the corporation. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used.

(c) Where the food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such food; such as "Manufactured for _____", "Distributed by _____", or any other wording that expresses the facts.

(d) The statement of the place of business shall include the street address, city, State, and ZIP code; however, the street address may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the ZIP code shall apply only to consumer commodity labels developed or revised after the effective date of this section. In the case of nonconsumer packages, the ZIP code shall appear either on the label or the labeling (including invoice).

(e) If a person manufacturers, packs, or distributes a food at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where such food was manufactured or packed or is to be distributed, unless such statement would be misleading.

§ 101.6 Label designation of ingredients for standardized foods.

(a) There is significant consumer interest that the labels of standardized foods bear complete information on the ingredients contained in the food. In the absence of legal authority to require that the label bear such information, the Food and Drug Administration encourages all manufacturers, packers, and distributors to voluntarily make such disclosure.

(b) The Food and Drug Administration intends to amend the definitions and standards of identity of food by setting into motion as rapidly as possible the provisions of section 401 of the act to require label declaration of all optional ingredients with the exception of optional spices, flavorings, and colorings which may continue to be designated as such without specific ingredient declaration.

(c) Statutory authority does not exist to require the declaration of mandatory ingredients on the label of standardized foods.

(d) The requirement (set forth in some of the definitions and standards of identity for food) that designated optional ingredients such as spices, flavorings, colorings, emulsifiers, flavor enhancers, stabilizers, preservatives, and sweeteners be declared in a specified manner on the label wherever the name of the standardized food appears on the label so conspicuously as to be easily seen under customary conditions of purchase shall not apply to any manufacturer, packer, or distributor of a standardized food who voluntarily labels such food in the manner indicated by section 403(i) of the act (21 U.S.C. 343(i)), and the regulations promulgated thereunder, and who otherwise complies with such definition and standard. Words and statements that significantly differentiate between several foods complying with the same standard by describing the optional forms or varieties, the packing medium, and significant characterizing ingredients present in the food, shall continue to be declared in the manner as required by the particular standard.

§ 101.8 Labeling of food with number of servings.

(a) The label of any package of a food which bears a representation as to the number of servings contained in such package shall bear in immediate conjunction with such statement, and in the same size type as is used for such statement, a statement of the net quantity (in terms of weight, measure, or numerical count) of each such serving; however, such statement may be expressed in terms that differ from the terms used in the required statement of net quantity of contents (for example, cupfuls, tablespoonfuls, etc.) when such differing term is common to cookery and describes a constant quantity. Such statement may not be misleading in any particular. A statement of the number of units in a package is not in itself a statement of the number of servings.

(b) If there exists a voluntary product standard promulgated pursuant to the procedures found in 15 CFR Part 10 by the Department of Commerce, quantitatively defining the meaning of the term "serving" with respect to a particular food, then any label representation as to the number of servings in such packaged food shall correspond with such quantitative definition. (Copies of published standards are available upon request from the National Bureau of

Standards, Department of Commerce, Washington, DC 20234.)

§ 101.9 Nutrition labeling of food.

(a) Nutrition information relating to food may be included on the label and in the labeling of a product: *Provided,* That it conforms to the requirements of this section. Except as provided in paragraph (h) of this section, inclusion of any added vitamin, mineral, or protein in a product or of any nutrition claim or information, other than sodium content, on a label or in advertising for a food subjects the label to the requirements of this section, and in labeling for a food subjects the label and that labeling to the requirements of this section.

(1) Solicitation of requests for nutrition information by a statement "For nutrition information write to _____" on the label or in the labeling or advertising for a food, or providing such information in a direct written reply to a solicited or unsolicited request, does not subject the label or the labeling to the requirements of this section if no other nutrition claim is made on the label or in other labeling or advertising, if the reply to the request conforms to the requirements of this section, and if no vitamin, mineral, or protein is added to the food.

(2) If any vitamin and/or mineral is added to a food so that a single serving provides 50 percent or more of the U.S. Recommended Daily Allowance (U.S. RDA) for adults and children 4 years or more of age, as specified in § 105.3 of this chapter, of any one of the added vitamins and/or minerals, unless such addition is permitted or required in other regulations, e.g., a standard of identity or nutritional quality guideline, or is otherwise exempted by the Commissioner the food shall conform to the standard or identity set forth in § 105.85 of this chapter, and shall also conform to the labeling established in § 105.85 of this chapter, except that the labeling established in paragraph (c) of this section including the order for listing vitamins and minerals established in paragraph (c)(7)(iv) of this section, shall be used in lieu of the labeling established in § 105.85(i)(1) of this chapter.

(b) All nutrient quantities (including vitamins, minerals, calories, protein, carbohydrate, and fat) shall be declared in relation to the average or usual serving or, where the food is customarily not consumed directly, in relation to the average or usual portion. Another column of figures may be used to declare the nutrient quantities in relation to the average or usual amount consumed on a daily basis, in the same format required in paragraph (c) of this section for the serving (portion), where reliable data have established that the food is customarily consumed more than once during the day and the average or usual amount so consumed.

(1) The term "serving" means that reasonable quantity of food suited for or practicable of consumption as part of a meal by an adult male engaged in light physical activity, or by an infant or child under 4 years of age when the article purports or is represented to be for consumption by an infant or child under 4 years of age. The term "portion" means the amount of a food customarily used only as an ingredient in the preparation of a meal component (e.g., ½ cup flour, ½ tablespoon cooking oil or ¼ cup tomato paste). A label statement regarding a serving (portion) shall be in terms of a convenient unit of such food or a convenient unit of measure that can be easily identified as an average or usual serving (portion) and can be readily understood by purchasers of such food (e.g., a serving (portion) may be expressed in slices, cookies, or wafers; or in terms of ounces, fluid ounces, teaspoonfuls, tablespoonfuls, or cupfuls).

(2) A teaspoonful shall be considered to mean 5 milliliters (approximately one-sixth fluid ounce) in volume; a tablespoon shall be considered to mean 15 milliliters (approximately one-half fluid ounce) in volume; and a cupful shall be considered to mean 240 milliliters (approximately 8 fluid ounces) in volume. The weight of the serving (portion) may also be expressed in grams.

(3) The declaration of nutrient quantities shall be on the basis of the food as packaged. Another column of figures may be used to declare the nutrient quantities on the basis of the food as consumed after cooking or other preparation, in the same format required in paragraph (c) of this section for the food alone: *Provided,* That the specific method of cooking or other preparation shall be disclosed in a prominent statement immediately following the information required by paragraph (c) of this section.

(c) The declaration of nutrition information on the label and in labeling shall contain the following information in the following order, using the headings specified, under the overall heading of "Nutrition Information Per Serving (Portion)." The terms "Per Serving (Portion)" are optional and may follow or be placed directly below the terms "Nutrition Information."

(1) "Serving (portion) size": A statement of the serving (portion) size.

(2) "Servings (portions) per container": The number of servings (portions) per container.

(3) "Caloric content" or "Calories": A statement of the caloric content per serving (portion), expressed to the nearest 2-calorie increment up to and including 20 calories, 5-calorie increment above 20 calories and up to and including 50 calories, and 10-calorie increment above 50 calories. Caloric content shall be determined by the Atwater method as described in A. L. Merrill and B. K. Watt, "Energy Value of Foods—Basis and Derivation," USDA Handbook 74 (1955).[1] Caloric content may be calculated on the basis of 4, 4, and 9 calories per gram for protein, carbohydrate, and fat respectively unless the use of these values gives a caloric value more than 20 percent greater than the caloric value obtained when using the more accurate values determined by use of the Atwater method as found in USDA Handbook 74 (1955).[1]

(4) "Protein content" or "Protein": A statement of the number of grams of protein in a serving (portion), expressed to the nearest gram. Protein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis of the Association of Official Analytical Chemists, 11th edition, 1970,[2] except when the official procedure for a specific food requires another factor.

(5) "Carbohydrate content" or "Carbohydrate": A statement of the number of grams of carbohydrate in a serving (portion) expressed to the nearest gram.

(6) "Fat content" or "Fat": A statement of the number of grams of fat in a serving (portion) expressed to the nearest gram. Fatty acid composition, cholesterol content, and sodium content may also be declared in compliance with §§ 101.25 and 105.69 of this chapter.

(i) When fatty acid composition is declared, the information on fatty acids required by § 101.25(c) shall be placed on the label immediately following the statement of fat content. The declaratory information statement required by § 101.25(d) shall be placed either immediately following the statement on fat and fatty acids or shall be appropriately referenced by symbol and placed immediately following the completed nutrition information statement.

(ii) When cholesterol content is declared, the information on cholesterol required by § 101.25(b) shall immediately follow the statement on fat content (and fatty acids, if stated). The declaratory information statement required by § 101.25(d) shall be placed either immediately following the statement on cholesterol or shall be appropriately referenced by symbol and placed immediately following the completed nutrition information statement.

(iii) When both fatty acid and cholesterol information are provided, the declaratory information statement may be combined as permitted by § 101.25(d).

(iv) When sodium is declared, the information on sodium required by § 105.69 of this chapter shall be placed on the label immediately following the statement on fat content (and fatty acid and/or cholesterol, if stated).

(7) "Percentage of U.S. Recommended Daily Allowances (U.S. RDA)": A statement of the amount per serving (portion) of the protein, vitamins, and minerals, as described in this paragraph (c)(7), expressed in percentage of the U.S. Recommended Daily Allowance (U.S. RDA).

(i) The percentages shall be expressed in 2-percent increments up to and in-

[1] Copies may be obtained from: Division of Nutrition (HFF-260), Bureau of Foods, Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204.

[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

cluding the 10-percent level, 5-percent increments above 10 percent and up to and including the 50-percent level, and 10-percent increments above the 50-percent level. Nutrients present in amounts less than 2 percent of the U.S. RDA may be indicated by a zero, or by an asterisk referring to another asterisk placed at the bottom of the table and followed by the statement "contains less than 2 percent of the U.S. RDA of this (these) nutrient (nutrients)." However, when a product contains less than 2 percent of the U.S. RDA for each of five or more of the eight nutrients specified in paragraph (c)(7)(iii) of this section, the manufacturer or distributor may choose to declare no more than three of those nutrients and none of the remainder listed in paragraph (c)(7)(iv) of this section. The statement "contains less than 2 percent of the U.S. RDA of _____", listing whichever of the eight nutrients are present at less than 2 percent of the U.S. RDA and have not been declared, shall directly follow the declared nutrient in the same type size. Any nutrient declared shall always appear in the order established in paragraph (c)(7)(iv) of this section.

(ii) The declaration of protein, which shall come first, shall be a statement of the amount per serving (portion) of protein, expressed as a percentage of the U.S. RDA.

(*a*) The U.S. RDA of the protein in a food product is 45 grams if the protein efficiency ration (PER) of the total protein in the product is equal to or greater than that of casein, and 65 grams if the PER of the total protein in the product is less than that of casein. The percentage of the U.S. RDA shall be declared as described in paragraph (c)(7)(i) of this section.

(*b*) Total protein with a PER less than 20 percent of the PER of casein may not be stated on the label in terms of percentage U.S. RDA, and the statement of protein content in grams per serving (portion) under paragraph (c)(4) of this section shall be modified by the statement "not a significant source of protein" immediately adjacent to the protein content statement regardless of the actual amount of protein present.

(iii) The declaration of vitamins and minerals as a percent of the U.S. RDA which shall follow the protein declaration, shall include vitamin A, vitamin C, thiamine, riboflavin, niacin, calcium, and iron, in that order, and shall include any of the other vitamins and minerals listed in paragraph (c)(7)(iv) of this section when they are added and may list any of the other vitamins and minerals listed in paragraph (c)(7)(iv) of this section when they are naturally occurring in the order listed therein.

(iv) The following U.S. Recommended Daily Allowances (U.S. RDA) and nomenclature are established for these vitamins and minerals, essential in human nutrition:

Vitamin A, 5,000 International Units.
Vitamin C, 60 milligrams.[3]
Thiamine, 1.5 milligrams.[3]
Riboflavin, 1.7 milligrams.[3]
Niacin, 20 milligrams.
Calcium, 1.0 gram.
Iron, 18 milligrams.
Vitamin D, 400 International Units.
Vitamin E, 30 International Units.
Vitamin B_6, 2.0 milligrams.
Folic acid, 0.4 milligrams.
Vitamin B_{12}, 6 micrograms.
Phosphorus, 1.0 gram.
Iodine, 150 micrograms.
Magnesium, 400 milligrams.
Zinc, 15 milligrams.
Copper, 2 milligrams.
Biotin, 0.3 milligram.
Pantothenic acid, 10 milligrams.

These nutrients and levels have been derived by the Food and Drug Administration from the "Recommended Dietary Allowances," published by the Food and Nutrition Board, National Academy of Sciences-National Research Council, and are subject to amendment from time to time as more information on human nutrition becomes available.

(v) No claim may be made that a food is a significant source of a nutrient unless that nutrient is present in the food at a level equal to or in excess of 10 percent of the U.S. RDA in a serving (portion). No claim may be made that a food is nutritionally superior to another food unless it contains at least 10 percent more of the U.S. RDA of the claimed nutrient per serving (portion).

(d) Products with separately packaged ingredients or to which other ingredients are added by the user may be labeled as follows:

(1) If a product is comprised of two or more separately packaged ingredients enclosed in an outer container, nutrition labeling of the total product shall be located on the outer container to provide information for the consumer at the point of purchase. However, when two or more food products are simply combined together in such a manner that no outer container is used, or no outer label is available, each product shall have its own nutrition information, e.g., two boxes taped together or two cans combined in a clear plastic overwrap.

(2) If a food is commonly combined with another ingredient(s) before eating and directions for such combination are provided, another column of figures may be used to provide a list of the nutrient contents for the final combination in the same format required in paragraph (c) of this section for the food alone (e.g., a dry ready-to-eat cereal may be described with one set of percentage U.S. RDA values for the cereal as sold (per ounce), and another set for the cereal and milk as suggested in the label (per ounce of cereal and one-half cup of vitamin D fortified whole milk); and a cake mix may be labeled with one set of percentage U.S. RDA values for the dry mix (per serving), and another set for a serving of the final cake when prepared). The type and quantity of the other ingredient(s) to be added by the user to the product shall be specified.

(e) Compliance with this section shall be determined as follows:

(1) A collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, or in the absence of any common container code or marking a day's production, constitutes a "lot."

(2) The sample for nutrient analysis shall consist of a composite of 12 subsamples (consumer units), taken one from each of 12 different randomly chosen shipping cases, to be representative of a lot. Composites shall be analyzed by Association of Official Analytical Chemists (AOAC) methods where available or, if no AOAC method is available, by reliable and appropriate analytical procedures. Alternative methods of analysis may be submitted to the Food and Drug Administration to determine their acceptability.

(3) Two classes of nutrients are defined for purposes of compliance:

Class I. Added nutrients in fortified or fabricated foods.
Class II. Naturally occurring (indigenous) nutrients.

If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food, the total amount of such nutrient in the final food product is subject to Class II requirements unless the same nutrient is also added.

(4) A food with a label declaration of a vitamin, mineral, or protein shall be deemed to be misbranded under section 403(a) of the act unless it meets the following requirements:

(i) *Class I vitamin, mineral, or protein.* The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

(ii) *Class II vitamin, mineral, or protein.* The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label.

Provided, That no regulatory action will be based on a determination of a nutrient value which falls below this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

(5) A food with a label declaration of calories, carbohydrates, or fat shall be deemed to be misbranded under section

[3] The following synonyms may be added in parentheses immediately following the name of the vitamin:

Vitamin C	Ascorbic acid
Folic acid	Folacin
Riboflavin	Vitamin B_2
Thiamine	Vitamin B_1

403(a) of the act unless the nutrient content of the composite is no greater than 20 percent in excess of the value for that nutrient declared on the label.

(6) Reasonable excesses of a vitamin, mineral, or protein over labeled amounts are acceptable within good manufacturing practices. Reasonable deficiencies of calories or fat under labeled amounts are acceptable within good manufacturing practices.

(f) Nutrition information provided by a manufacturer or distributor directly to professionals (e.g., physicians, dietitians, educators) may vary from the requirements of this section but shall also contain or have attached to it the nutrition information exactly as required by this section.

(g) The location of nutrition information on a label shall be in compliance with § 101.2.

(h) The following foods are exempt from this section or are subject to special labeling requirements:

(1) (i) Except where expressly covered by § 105.65 of this chapter, infant, baby, and junior-type food promoted for infants and children under 4 years of age shall include nutrition information on the label and in labeling in compliance with this section, except that the U.S. Recommended Daily Allowance (U.S. RDA) levels for infants from birth to 12 months of age or for children under 4 years of age contained in § 105.3(b) of this chapter shall be used in lieu of the U.S. RDA levels contained in paragraph (c)(7)(iv) of this section.

(ii) Both the U.S. RDA levels for infants from birth to 12 months of age and the U.S. RDA values for children under 4 years of age may be declared for foods represented or intended for use by both infants and children under 4 years of age. If such dual declaration is used on any label, it shall also be included in all labeling, and equal prominence shall be given to both values in all promotional material.

(iii) For the purposes of labeling these foods with a percent of the U.S. RDA for protein for infants, a value of 18 grams of protein shall be the U.S. RDA value for protein with a protein efficiency ratio (PER) equal to or greater than casein, and 25 grams if the PER of the protein is less than the PER of casein but greater than 40 percent of casein. For purposes of labeling foods for children under 4 years of age with a percent of the U.S. RDA for protein, a value of 20 grams of protein shall be the U.S. RDA value for protein with a PER equal to or greater than casein, and 28 grams if the PER of the protein is less than the PER of casein but greater than 20 percent of casein.

(iv) Total protein with a PER less than 40 percent of the PER of casein may not be stated on the label in terms of percentage U.S. RDA for infants, and the statement of protein content in grams per serving under paragraph (c)(4) of this section shall be modified by the statement "not a significant source of protein for infants" immediately adjacent to the protein content statement regardless of the actual amount of protein present.

(2) Dietary supplements, the nutrients of which consist solely of vitamins and/or minerals, shall be labeled in compliance with §§ 105.77 and 105.85 of this chapter, except that the labeling of a dietary supplement in food form, e.g., a breakfast cereal, shall conform to the labeling established in paragraph (c) of this section, including the order for listing vitamins and minerals established in paragraph (c)(7)(iv) of this section, in lieu of the labeling established in § 105.85 (i)(1) of this chapter.

(3) Any food represented for use as the sole item of the diet shall be labeled in compliance with Part 105 of this chapter.

(4) Foods represented for use solely under medical supervision to meet nutritional requirements in specific medical conditions shall be labeled in compliance with Part 105 of this chapter.

(5) Iodized salt shall be labeled in compliance with § 100.155 of this chapter and when used in a food does not subject that food to labeling under this section if it is declared in the ingredient statement by its name (iodized salt) and neither iodine nor iodized salt is otherwise referred to on the label or in labeling or advertising.

(6) A nutrient(s) included in food solely for technological purposes may be declared solely in the ingredient statement, without complying with this section, if the nutrient(s) is otherwise not referred to on the label or in labeling or in advertising.

(7) A standardized food containing an added nutrient(s), e.g., enriched flour, and included in another food as a component may be declared in the ingredient statement by its standardized name, without compliance with this section, if neither the nutrient(s) nor the component is otherwise referred to on the label or in labeling or in advertising.

(8) Food products shipped in bulk form for use solely in the manufacture of other foods and not for distribution to consumers in such bulk form or container.

(9) Food products containing an added vitamin, mineral, or protein, or for which a nutritional claim is made on the label or in labeling or in advertising, which are supplied for institutional food service use only: *Provided,* That the manufacturer or distributor provides the nutrition information required by this section directly to those institutions on a current basis.

(10) Fresh fruits and fresh vegetables, pending promulgation of specific labeling requirements for these products.

(i) A food labeled under the provisions of this section shall be deemed to be misbranded under sections 201(n) and 403(a) of the act if its labeling represents, suggests, or implies:

(1) That the food because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom.

(2) That a balanced diet of ordinary foods cannot supply adequate amounts of nutrients.

(3) That the lack of optimum nutritive quality of a food, by reason of the soil on which that food was grown, is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(4) That the storage, transportation, processing or cooking of a food is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(5) That the food has dietary properties when such properties are of no significant value or need in human nutrition. Ingredients or products such as rutin, other bioflavonoids, para-aminobenzoic acid, inositol, and similar substances which have in the past been represented as having nutritional properties but which have not been shown to be essential in human nutrition may not be combined with vitamins and/or minerals, added to food labeled in accordance with this section, or otherwise used or represented in any way which states or implies nutritional benefit. Ingredients or products of this type may be marketed as individual products or mixtures thereof: *Provided,* That the possibility of nutritional, dietary, or therapeutic value is not stated or implied, e.g., their labeling does not state that their usefulness in human nutrition has not been established and does not otherwise disclaim nutritional, dietary, or therapeutic value.

(6) That a natural vitamin in a food is superior to an added or synthetic vitamin, or to differentiate in any way between vitamins naturally present from those added.

(Secs. 201(n), 403(a), 701(a), 52 Stat. 1040–1042, 1047, 1055; 21 U.S.C. 321(n), 343(a), 371(a).)

§ 101.10 Nutrition labeling of restaurant foods.

A nutrition claim or nutrition information concerning a combination of restaurant foods, e.g., the total nutritional value of a meal consisting of a hamburger, french fries, and milk shake, may be included in advertising and/or in labeling (other than labels), without causing nutrition information to be required on the label(s) of each article of food: *Provided,* That complete nutrition information for the combination of foods (the combination as an entity without the nutritional value of each article being specified) in the format established by § 101.9(c) is effectively displayed to the customer both when he orders the food and when he consumes the food. This statement of policy does not apply to food dispensed in automatic vending machines.

(Secs. 201, 403, 701(a), 52 Stat. 1040–1042 as amended, 1047–1048 as amended, 1055 (21 U.S.C. 321, 343, 371(a)).)

§ 101.15 Food; prominence of required statements.

(a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 403(f) of the act by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is pre-

sented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 403 (e) or (i) of the act, shall apply if such insufficiency is caused by:

(1) The use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(2) The use of label space to give greater conspicuousness to any word, statement, or other information than is required by section 403(f) of the act; or

(3) The use of label space for any representation in a foreign language.

(c)(1) All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language: *Provided, however*, That in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language: *Provided, however*, That individual serving-size packages of foods containing no more than 1½ avoirdupois ounces or no more than 1½ fluid ounces served with meals in restaurants, institutions, and passenger carriers and not intended for sale at retail are exempt from the requirements of this paragraph (c)(2), if the only representation in the foreign language(s) is the name of the food.

(3) If any article of labeling (other than a label) contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on such article of labeling.

§ 101.17 Food labeling warning statements.

(a) *Self-pressurized containers.* (1) The label of a food packaged in a self-pressurized container and intended to be expelled from the package under pressure shall bear the following warning:

WARNING—Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120° F. Keep out of reach of children.

(2) In the case of products intended for use by children, the phrase "except under adult supervision" may be added at the end of the last sentence in the warning required by paragraph (a)(1) of this section.

(3) In the case of products packaged in glass containers, the word "break" may be substituted for the word "puncture" in the warning required by paragraph (a)(1) of this section.

(4) The words "Avoid spraying in eyes" may be deleted from the warning required by paragraph (a)(1) of this section in the case of a product not expelled as a spray.

(b) *Self-pressurized containers with halocarbon or hydrocarbon propellants.* (1) In addition to the warning required by paragraph (a) of this section, the label of a food packaged in a self-pressurized container in which the propellant consists in whole or in part of a halocarbon or a hydrocarbon shall bear the following warning:

WARNING—Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

(2) The warning required by paragraph (b)(1) of this section is not required for the following products:

(i) Products expelled in the form of a foam or cream, which contain less than 10 percent propellant in the container.

(ii) Products in a container with a physical barrier that prevents escape of the propellant at the time of use.

(iii) Products of a net quantity of contents of less than 2 ounces that are designed to release a measured amount of product with each valve actuation.

(iv) Products of a net quantity of contents of less than one-half ounce.

§ 101.18 Misbranding of food.

(a) Among representations in the labeling of a food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device, or cosmetic.

(b) The labeling of a food which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

(c) Among representations in the labeling of a food which render such food misbranded is any representation that expresses or implies a geographical origin of the food or any ingredient of the food except when such representation is either:

(1) A truthful representation of geographical origin.

(2) A trademark or trade name provided that as applied to the article in question its use is not deceptively misdescriptive. A trademark or trade name composed in whole or in part of geographical words shall not be considered deceptively misdescriptive if it:

(i) Has been so long and exclusively used by a manufacturer or distributor that it is generally understood by the consumer to mean the product of a particular manufacturer or distributor; or

(ii) Is so arbitrary or fanciful that it is not generally understood by the consumer to suggest geographic origin.

(3) A part of the name required by applicable Federal law or regulation.

(4) A name whose market significance is generally understood by the consumer to connote a particular class, kind, type, or style of food rather than to indicate geographical origin.

Subpart B—Specific Food Labeling Requirements

§ 101.22 Foods; labeling of spices, flavorings, colorings and chemical preservatives.

(a)(1) The term "artificial flavor" or "artificial flavoring" means any substance, the function of which is to impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products, or fermentation products thereof. Artificial flavor includes the substances listed in §§ 172.515(b) and 182.60 of this chapter except where these are derived from natural sources.

(2) The term "spice" means any aromatic vegetable substance in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, such as onions, garlic and celery; whose significant function in food is seasoning rather than nutritional; that is true to name; and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in § 182.10 of this chapter, such as the following:

Allspice	Marjoram
Anise	Mustard flour
Basil	Nutmeg
Bay leaves	Oregano
Caraway seed	Paprika
Cardamon	Parsley
Celery seed	Pepper, black
Chervil	Pepper, white
Cinnamon	Pepper, red
Cloves	Rosemary
Coriander	Saffron
Cumin seed	Sage
Dill seed	Savory
Fennel seed	Star aniseed
Fenugreek	Tarragon
Ginger	Thyme
Horseradish	Turmeric
Mace	

Paprika, turmeric, and saffron or other spices which are also colors, shall be declared as "spice and coloring" unless declared by their common or usual name.

(3) The term "natural flavor" or "natural flavoring" means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in §§ 182.10, 182.20, 182.30, 182.40, and 182.50 of this chapter, and the substances listed in § 172.510 of this chapter.

(4) The term "artificial color" or "artificial coloring" means any "color additive" as defined in § 8.1(f) of this chapter.

(5) The term "chemical preservative" means any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties.

(b) A food which is subject to the requirements of section 403(k) of the act shall bear labeling, even though such food is not in package form.

(c) A statement of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the food, or on its container or wrapper, or on any two or all of these, as may be necessary to render such statement likely to be read by the ordinary individual under customary conditions of purchase and use of such food.

(d) A food shall be exempt from compliance with the requirements of section 403(k) of the act if it is not in package form and the units thereof are so small that a statement of artificial flavoring, artificial coloring, or chemical preservative, as the case may be, cannot be placed on such units with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

(e) A food shall be exempt while held for sale from the requirements of section 403(k) of the act (requiring label statement of any artificial flavoring, artificial coloring, or chemical preservatives) if said food, having been received in bulk containers at a retail establishment, is displayed to the purchaser with either (1) the labeling of the bulk container plainly in view or (2) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to section 403(k).

(f) A fruit or vegetable shall be exempt from compliance with the requirements of section 403(k) of the act with respect to a chemical preservative applied to the fruit or vegetable as a pesticide chemical prior to harvest.

(g) A flavor shall be labeled in the following way when shipped to a food manufacturer or processor (but not a consumer) for use in the manufacture of a fabricated food, unless it is a flavor for which a standard of identity has been promulgated, in which case it shall be labeled as provided in the standard:

(1) If the flavor consists of one ingredient, it shall be declared by its common or usual name.

(2) If the flavor consists of two or more ingredients, the label either may declare each ingredient by its common or usual name or may state "All flavor ingredients contained in this product are approved for use in a regulation of the Food and Drug Administration." Any flavor ingredient not contained in one of these regulations, and any nonflavor ingredient, shall be separately listed on the label.

(3) In cases where the flavor contains a solely natural flavor(s), the flavor shall be so labeled, e.g., "strawberry flavor", "banana flavor", or "natural strawberry flavor". In cases where the flavor contains both a natural flavor and an artificial flavor, the flavor shall be so labeled, e.g., "natural and artificial strawberry flavor". In cases where the flavor contains a solely artificial flavor(s), the flavor shall be so labeled, e.g., "artificial strawberry flavor".

(h) The label of a food to which flavor is added shall declare the flavor in the statement of ingredients in the following way:

(1) Spice, natural flavor, and artificial flavor may be declared as "spice", "natural flavor", or "artificial flavor", or any combination thereof, as the case may be.

(2) An incidental additive in a food, originating in a spice or flavor used in the manufacture of the food, need not be declared in the statement of ingredients if it meets the requirements of § 101.100(a)(3).

(3) Substances obtained by cutting, grinding, drying, pulping, or similar processing of tissues derived from fruit, vegetable, meat, fish, or poultry, e.g., powdered or granulated onions, garlic powder, and celery powder, are commonly understood by consumers to be food rather than flavor and shall be declared by their common or usual name.

(4) Any salt (sodium chloride) used as an ingredient in food shall be declared by its common or usual name "salt."

(5) Any monosodium glutamate used as an ingredient in food shall be declared by its common or usual name "monosodium glutamate."

(6) Any pyroligneous acid or other artificial smoke flavors used as an ingredient in a food may be declared as artificial flavor or artificial smoke flavor. No representation may be made, either directly or implied, that a food flavored with pyroligneous acid or other artificial smoke flavor has been smoked or has a true smoked flavor, or that a seasoning sauce or similar product containing pyroligneous acid or other artificial smoke flavor and used to season or flavor other foods will result in a smoked product or one having a true smoked flavor.

(i) If the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor(s), by word, vignette, e.g., depiction of a fruit, or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor shall be considered the characterizing flavor and shall be declared in the following way:

(1) If the food contains no artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla", in letters not less than one-half the height of the letters used in the name of the food, except that:

(i) If the food is one that is commonly expected to contain a characterizing food ingredient, e.g., strawberries in "strawberry shortcake", and the food contains natural flavor derived from such ingredient and an amount of characterizing ingredient insufficient to independently characterize the food, or the food contains no such ingredient, the name of the characterizing flavor may be immediately preceded by the word "natural" and shall be immediately followed by the word "flavored" in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "natural strawberry flavored shortcake," or "strawberry flavored shortcake".

(ii) If none of the natural flavor used in the food is derived from the product whose flavor is simulated, the food in which the flavor is used shall be labeled either with the flavor of the product from which the flavor is derived or as "artificially flavored."

(iii) If the food contains both a characterizing flavor from the product whose flavor is simulated and other natural flavor which simulates, resembles or reinforces the characterizing flavor, the food shall be labeled in accordance with the introductory text and paragraph (i)(1)(i) of this section and the name of the food shall be immediately followed by the words "with other natural flavor" in letters not less than one-half the height of the letters used in the name of the characterizing flavor.

(2) If the food contains any artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name(s) of the characterizing flavor, in letters not less than one-half the height of the letters used in the name of the food and the name of the characterizing flavor shall be accompanied by the word(s) "artificial" or "artificially flavored", in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "artificial vanilla", "artificially flavored strawberry", or "grape artificially flavored".

(3) Wherever the name of the characterizing flavor appears on the label

(other than in the statement of ingredients) so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, without any intervening written, printed, or graphic matter, except:

(i) Where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor; and

(ii) If the finished product contains more than one flavor subject to the requirements of this paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such food, e.g., "artificially flavored vanilla and strawberry".

(iii) If the finished product contains three or more distinguishable characterizing flavors, or a blend of flavors with no primary recognizable flavor, the flavor may be declared by an appropriately descriptive generic term in lieu of naming each flavor, e.g., "artificially flavored fruit punch".

(4) A flavor supplier shall certify, in writing, that any flavor he supplies which is designated as containing no artificial flavor does not, to the best of his knowledge and belief, contain any artificial flavor, and that he has added no artificial flavor to it. The requirement for such certification may be satisfied by a guarantee under section 303(c)(2) of the act which contains such a specific statement. A flavor used shall be required to make such a written certification only where he adds to or combines another flavor with a flavor which has been certified by a flavor supplier as containing no artificial flavor, but otherwise such user may rely upon the supplier's certification and need make no separate certification. All such certifications shall be retained by the certifying party throughout the period in which the flavor is supplied and for a minimum of three years thereafter, and shall be subject to the following conditions:

(i) The certifying party shall make such certifications available upon request at all reasonable hours to any duly authorized office or employee of the Food and Drug Administration or any other employee acting on behalf of the Secretary of Health, Education, and Welfare. Such certifications are regarded by the Food and Drug Administration as reports to the government and as guarantees or other undertakings within the meaning of section 301(h) of the act and subject the certifying party to the penalties for making any false report to the government under 18 U.S.C. 1001 and any false guarantee or undertaking under section 303(a) of the act. The defenses provided under section 303(c)(2) of the act shall be applicable to the certifications provided for in this section.

(ii) Wherever possible, the Food and Drug Administration shall verify the accuracy of a reasonable number of certifications made pursuant to this section, constituting a representative sample of such certifications, and shall not request all such certifications.

(iii) Where no person authorized to provide such information is reasonably available at the time of inspection, the certifying party shall arrange to have such person and the relevant materials and records ready for verification as soon as practicable: *Provided*, That, whenever the Food and Drug Administration has reason to believe that the supplier or user may utilize this period to alter inventories or records, such additional time shall not be permitted. Where such additional time is provided, the Food and Drug Administration may require the certifying party to certify that relevant inventories have not been materially disturbed and relevant records have not been altered or concealed during such period.

(iv) The certifying party shall provide, to an officer or representative duly designated by the Secretary, such qualitative statement of the composition of the flavor or product covered by the certification as may be reasonably expected to enable the Secretary's representatives to determine which relevant raw and finished materials and flavor ingredient records are reasonably necessary to verify the certifications. The examination conducted by the Secretary's representative shall be limited to inspection and review of inventories and ingredient records for those certifications which are to be verified.

(v) Review of flavor ingredient records shall be limited to the qualitative formula and shall not include the quantitative formula. The person verifying the certifications may make only such notes as are necessary to enable him to verify such certification. Only such notes or such flavor ingredient records as are necessary to verify such certification or to show a potential or actual violation may be removed or transmitted from the certifying party's place of business: *Provided*, That, where such removal or transmittal is necessary for such purposes the relevant records and notes shall be retained as separate documents in Food and Drug Administration files, shall not be copied in other reports, and shall not be disclosed publicly other than in a judicial proceeding brought pursuant to the act or 18 U.S.C. 1001.

(j) A food to which a chemical preservative(s) is added shall, except when exempt pursuant to § 101.100 bear a label declaration stating both the common or usual name of the ingredient(s) and a separate description of its function, e.g., "preservative", "to retard spoilage", "a mold inhibitor", "to help protect flavor" or "to promote color retention".

(Secs. 402, 403, 409, 701(a), 702, 703, 704, 52 Stat. 1046, 1047, 1048–1049 as amended, 1055, 1056–1057 as amended; 21 U.S.C. 342, 343, 348, 371(a), 372, 373, 374.)

§ 101.25 Labeling of foods in relation to fat and fatty acid and cholesterol content.

(a) Implicit or explicit claims for the value of food in preventing or treating heart or artery disease can be misleading to consumers. However, a significant segment of the medical community is recommending that individuals modify their total diet by eliminating certain foods or by replacing certain foods with others in order to effect changes in the levels of blood components. Although there have been no definitive studies which have demonstrated beyond doubt that extensive changes in the consumption of fat and cholesterol by the general public are desirable, it is nevertheless appropriate to provide for informative labeling which will help individuals to identify foods for inclusion in fat-modified diets recommended by physicians. It is also appropriate to prohibit label statements which misrepresent specific foods as being, of themselves, of value in the control of the levels of these blood components or in the control of heart or artery disease.

(b) A food label or labeling may include a statement of the cholesterol content of the food: *Provided*, That it meets the following conditions:

(1) The food is labeled in compliance with the provisions of § 101.9.

(2) The following information is included in the following order, in accordance with the provisions of § 101.9(c)(6)(ii):

(i) The cholesterol content, stated to the nearest 5-milligram increment per serving.

(ii) The cholesterol content, stated to the nearest 5-milligram increment per 100 grams of the food.

(iii) The statement required by paragraph (d) of this section.

(c) A food label or labeling may include information on the fatty acid content of the food: *Provided*, That it meets the following conditions:

(1) The food contains 10 percent or more fat on a dry weight basis and not less than 2 grams of fat in an average serving. Any food containing less than 10 percent total fat on a dry weight basis and/or containing less than 2 grams of fat in a serving is not suitable for use by man as a means of regulating the intake of fatty acids.

(2) The food is labeled in compliance with § 101.9 and the following information is included in the following order in accordance with § 101.9(c)(6)(ii):

(i) The total fat content in terms of the percentage of the total calories in the food provided by fat with the heading "Percent of calories from fat".

(ii) The amount of fatty acids, calculated as the triglycerides, shall be stated in grams per serving to the nearest gram in the following two categories, stated with the following headings, in the following order, and displayed in equal prominence:

(*a*) *Cis,cis*-methylene-interrupted polyunsaturated fatty acids, stated as "Polyunsaturated";

(b) The sum of lauric, myristic, palmitic, and stearic acids, stated as "Saturated"; and

(iii) The statement required by paragraph (d) of this section.

(d) A food labeled in accordance with paragraph (b) or (c) of this section shall display the following statement on the label: "Information (or "this information") on fat (and/or cholesterol, where appropriate) content is provided for individuals who, on the advice of a physician, are modifying their dietary intake of fat (and/or cholesterol, where appropriate)."

(e) Compliance with this section shall be determined as follows:

(1) A collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking or, in the absence of any common container code or marking, a day's production, constitutes a "lot."

(2) The sample for analysis shall consist of a composite of 12 subsamples (consumer units), taken one from each of 12 different randomly chosen shipping cases, to be representative of a lot.

(3) Composites shall be analyzed for fat and saturated fatty acids by the methods of the Association of Official Analytical Chemists (AOAC). The methods for fat, fatty acids, and cholesterol will be those of the Association of Official Analytical Chemists (AOAC), or other reliable and appropriate methods. Alternative methods of analysis may be submitted to the Food and Drug Administration to determine their acceptability. The determination of *cis,cis*-methylene-interrupted polyunsaturated fatty acids will be the Canadian Food and Drug Directorate Method FA-59[1] for *cis,cis*-methylene-interrupted fatty acid.

(4) A food with a label declaration of cholesterol content shall be deemed to be misbranded under section 403(a) of the act if the content of the composite is greater than 20 percent in excess of the value for the cholesterol content declared on the label.

(5) A food with a label declaration of fat content shall be deemed to be misbranded under section 403(a) of the act if the content of the composite is greater than 20 percent in excess of the value for the fat content declared on the label or less than required by good manufacturing practices.

(6) A food with a label declaration of fatty acid content shall be deemed to be misbranded under section 403(a) of the act if the content of the composite is greater than 20 percent in excess of the value, or less than 80 percent of the value, for the fatty acid content declared on the label.

(f) Label statements made in accordance with paragraphs (b), (c), or (d) of this section shall comply with the requirements of § 101.2, but in no case may they be printed in larger than the minimum size type required by the provisions of § 101.105 for the declaration of net quantity of contents.

(g) No label or labeling may contain a claim indicating, suggesting, or implying that the product will prevent, mitigate, or cure heart or artery disease or any attendant condition. The principal display panel of the label may state "cholesterol (fat) information appears _____," the blank to be filled in with a phrase stating where the information is contained. The statement shall appear in one-sixteenth-inch type size or in the alternative in a type size no larger than one-half the minimum type size required for the declaration of net quantity of contents by the provisions of § 101.105 of this chapter.

(h) No statements relating to cholesterol, fat or fatty acids, other than those expressly permitted by this section may be made. Any label or labeling containing any statement concerning cholesterol, fat or fatty acids which is not in conformity with this section shall be deemed to be misbranded under sections 201(n) and 403(a) of the act.

§ 101.29 Labeling of kosher and kosher-style foods.

The term "kosher" should be used only on food products that meet certain religious dietary requirements. The precise significance of the phrase "kosher style" as applied to any particular product by the public has not been determined. There is a likelihood that the use of the term may cause the prospective purchaser to think that the product is "kosher." Accordingly, the Food and Drug Administration believes that use of the phrase should be discouraged on products that do not meet the religious dietary requirements.

(Sec. 402, 52 Stat. 1046; 21 U.S.C. 342)

§ 101.33 Label declaration of D-erythroascorbic acid when it is an ingredient of a fabricated food.

(a) The article D-erythroascorbic acid (D-araboascorbic acid, D-erythro-3-ketohexonic acid lactone) has sometimes been designated as D-isoascorbic acid. However, this designation is capable of misleading purchasers of food in which it is used as an ingredient because of the similarity of such designation to the chemical name and the common name of vitamin C, which is ascorbic acid. Ascorbic acid (vitamin C) is capable of preventing the deficiency disease scurvy, but D-isoascorbc acid is ineffective for this purpose.

(b) The Joint Committee on Nomenclature of the American Institute of Nutrition and the Society of Biological Chemists has considered this matter, and pursuant to the Committee's recommendation the respective scientific organizations approved a resolution to drop the use of the designation D-isoascorbic acid and to adopt as a common name the name erythorbic acid for D-erythroascorbic acid.

(c) The compound D-erythroascorbic acid is not specified as an ingredient of any food for which a standard has been established. For foods other than those for which standards have been established, section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act requires that ingredients be listed on labels by their common or usual names. If the label on a food that contains D-erythroascorbic acid designates that ingredient by the name erythorbic acid, the requirement that the label bear the common or usual name of the ingredient will be regarded as having been met.

(Sec. 403, 52 Stat. 1047, as amended (21 U.S.C. 343).)

§ 101.35 Notice to manufacturers and users of monosodium glutamate and other hydrolyzed vegetable protein products.

Following a review of various statements submitted by manufacturers and distributors of monosodium glutamate and various hydrolyzed plant protein products, the following conclusions have been reached:

(a) The facts submitted established that there are three classes of products to be considered:

(1) Purified monosodium glutamate.

(2) Hydrolyzed proteins (amino acid salts) from which none of the monosodium glutamate has been removed.

(3) Hydrolyzed proteins (amino acid salts), a byproduct in the manufacture of purified monosodium glutamate but from which a substantial proportion of the monosodium glutamate has been removed.

(b) [Reserved]

(c)(1) The substance described in paragraph (a)(2) of this section has long been designated as "hydrolyzed vegetable protein."

(2) The substance covered by paragraph (a)(3) of this section should have a distinctive name, since one of its original constituents has been partially removed. Manufacturers have suggested that this substance be described as "hydrolyzed vegetable protein with reduced monosodium glutamate content." This designation appears acceptable.

(d) While the substances referred to in paragraph (a) (2) and (3) of this section contain a number of amino acid salts as well as sodium chloride, monosodium glutamate is the ingredient which has been quite generally emphasized, and is best known to consumers under that name. No objection is offered under the Federal Food, Drug, and Cosmetic Act to the addition of a quantitative declaration on the labels of containers of such hydrolyzed vegetable protein or hydrolyzed vegetable protein with reduced monosodium glutamate content showing the percentage amounts of monosodium glutamate, the total of other amino acid salts, salt, and water, if in liquid form, all to be declared in the order of their decreasing percentages. If monosodium glutamate represents a smaller proportion of the substance than the other amino acid salts and salt (sodium chloride), it should be declared last in the list of ingredients.

[1] Copies may be obtained from: Division of Nutrition (HFF-260), Bureau of Foods, Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204.

(e) When the substances described in paragraph (a) (2) and (3) of this section are used as ingredients in a fabricated food, either may be declared as "salt and hydrolyzed vegetable protein" (or "salt and hydrolyzed plant protein") on the label of the fabricated food product: *Provided*, That where salt is declared as a separate ingredient of the fabricated food, in compliance with section 403(i)(2) of the act, the word "salt" need not be repeated in connection with the "hydrolyzed vegetable protein" (or "hydrolyzed plant protein") declaration.

Subparts C through E—[Reserved]

Subpart F—Exemptions From Food Labeling Requirements

§ 101.100 Food; exemptions from labeling.

(a) The following foods are exempt from compliance with the requirements of section 403(i)(2) of the act (requiring a declaration on the label of the common or usual name of each ingredient when the food is fabricated from two or more ingredients).

(1) An assortment of different items of food, when variations in the items that make up different packages packed from such assortment normally occur in good packing practice and when such variations result in variations in the ingredients in different packages, with respect to any ingredient that is not common to all packages. Such exemption, however, shall be on the condition that the label shall bear, in conjunction with the names of such ingredients as are common to all packages, a statement (in terms that are as informative as practicable and that are not misleading) indicating by name other ingredients which may be present.

(2) A food having been received in bulk containers at a retail establishment, if displayed to the purchaser with either (i) the labeling of the bulk container plainly in view or (ii) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to section 403(i)(2) of the act.

(3) Incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food. For the purposes of this paragraph (a)(3), incidental additives are:

(i) Substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect.

(ii) Processing aids, which are as follows:

(*a*) Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.

(*b*) Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food.

(c) Substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.

(iii) Substances migrating to food from equipment or packaging or otherwise affecting food that are not food additives as defined in section 201(s) of the act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act.

(b) A food repackaged in a retail establishment is exempt from the following provisions of the act if the conditions specified are met.

(1) Section 403(e)(1) of the act (requiring a statement on the label of the name and place of business of the manufacturer, packer, or distributor).

(2) Section 403(g)(2) of the act (requiring the label of a food which purports to be or is represented as one for which a definition and standard of identity has been prescribed to bear the name of the food specified in the definition and standard and, insofar as may be required by the regulation establishing the standard the common names of the optional ingredients present in the food), if the food is displayed to the purchaser with its interstate labeling clearly in view, or with a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required by these provisions.

(3) Section 403(i)(1) of the act (requiring the label to bear the common or usual name of the food), if the food is displayed to the purchaser with its interstate labeling clearly in view, or with a counter card, sign, or other appropriate device bearing prominently and conspicuously the common or usual name of the food, or if the common or usual name of the food is clearly revealed by its appearance.

(c) An open container (a container of rigid or semirigid construction, which is not closed by lid, wrapper, or otherwise other than by an uncolored transparent wrapper which does not obscure the contents) of a fresh fruit or fresh vegetable, the quantity of contents of which is not more than 1 dry quart, shall be exempt from the labeling requirements of sections 403(e), (g)(2) (with respect to the name of the food specified in the definition and standard), and (i)(1) of the act; but such exemption shall be on the condition that if two or more such containers are enclosed in a crate or other shipping package, such crate or package shall bear labeling showing the number of such containers enclosed therein and the quantity of the contents of each.

(d) Except as provided by paragraphs (e) and (f) of this section, a shipment or other delivery of a food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of section 403 (c), (e), (g), (h), (i), (j), and (k) of the act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such food is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such food in such establishment as will ensure, if such specifications are followed, that such food will not be adulterated or misbranded within the meaning of the act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until 2 years after the final shipment or delivery of such food from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

(3) The article is an egg product subject to a standard of identity promulgated in Part 160 of this chapter, is to be shipped under the conditions specified in paragraph (d)(1) or (2) of this section and for the purpose of pasteurization or other treatment as required in such standard, and each container of such egg product bears a conspicuous tag or label reading "Caution—This egg product has not been pasteurized or otherwise treated to destroy viable Salmonella microorganisms". In addition to safe and suitable bactericidal processes designed specifically for Salmonella destruction in egg products, the term "other treatment" in the first sentence of this paragraph shall include use in acidic dressings in the processing of which the pH is not above 4.1 and the acidity of the aqueous phase, expressed as acetic acid, is not less than 1.4 percent, subject also to the conditions that:

(i) The agreement required in paragraph (d)(2) of this section shall also state that the operator agrees to utilize such unpasteurized egg products in the processing of acidic dressings according to the specifications for pH and acidity set forth in this paragraph, agrees not to deliver the acidic dressing to a user until at least 72 hours after such egg product is incorporated in such acidic dressing, and agrees to maintain for inspection adequate records covering such processing for 2 years after such processing.

(ii) In addition to the caution statement referred to above, the container of such egg product shall also bear the statement "Unpasteurized ——— for use in acidic dressings only", the blank being filled in with the applicable name of the eggs or egg product.

(e) Conditions affecting expiration of exemptions: (1) An exemption of a shipment or other delivery of a food under paragraph (d) (1) or (3) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment become void ab initio if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(2) An exemption of a shipment or other delivery of a food under paragraph (d) (2) or (3) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by paragraph (d) (2) or (3) of this section.

(3) An exemption of a shipment or other delivery of a food under paragraph (d) (2) or (3) of this section shall expire:

(i) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the food constituting such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed; or

(ii) Upon refusal by the operator of the establishment where such food is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such paragraph.

(f) The word "processed" as used in this paragraph shall include the holding of cheese in a suitable warehouse at a temperature of not less than 35° F for the purpose of aging or curing to bring the cheese into compliance with requirements of an applicable definition and standard of identity. The exemptions provided for in paragraph (d) of this section shall apply to cheese which is, in accordance with the practice of the trade, shipped to a warehouse for aging or curing, on condition that the cheese is identified in the manner set forth in one of the applicable following paragraphs, and in such case the provisions of paragraph (e) of this section shall also apply:

(1) In the case of varieties of cheese for which definitions and standards of identity require a period of aging whether or not they are made from pasteurized milk, each such cheese shall bear on the cheese a legible mark showing the date at which the preliminary manufacturing process has been completed and at which date curing commences, and to each cheese, on its wrapper or immediate container, shall be affixed a removable tag bearing the statement "Uncured ——— cheese for completion of curing and proper labeling", the blank being filled in with the applicable name of the variety of cheese. In the case of swiss cheese, the date at which the preliminary manufacturing process had been completed and at which date curing commences is the date on which the shaped curd is removed from immersion in saturated salt solution as provided in the definition and standard of identity for swiss cheese, and such cheese shall bear a removable tag reading, "To be cured and labeled as 'swiss cheese,' but if eyes do not form, to be labeled as 'swiss cheese for manufacturing' ".

(2) In the case of varieties of cheeses which when made from unpasteurized milk are required to be aged for not less than 60 days, each such cheese shall bear a legible mark on the cheese showing the date at which the preliminary manufacturing process has been completed and at which date curing commences, and to each such cheese or its wrapper or immediate container shall be affixed a removable tag reading, "——— cheese made from unpasteurized milk. For completion of curing and proper labeling", the blank being filled in with the applicable name of the variety of cheese.

(3) In the case of cheddar cheese, washed curd cheese, colby cheese, granular cheese, and brick cheese made from unpasteurized milk, each such cheese shall bear a legible mark on the cheese showing the date at which the preliminary manufacturing process has been completed and at which date curing commences, and to each such cheese or its wrapper or immediate container shall be affixed a removable tag reading "——— cheese made from unpasteurized milk. For completion of curing and proper labeling, or for labeling as ——— cheese for manufacturing", the blank being filled in with the applicable name of the variety of cheese.

(g) The label declaration of a harmless marker used to identify a particular manufacturer's product may result in unfair competition through revealing a trade secret. Exemption from the label declaration of such a marker is granted, therefore, provided that the following conditions are met:

(1) The person desiring to use the marker without label declaration of its presence has submitted to the Commissioner of Food and Drugs full information concerning the proposed usage and the reasons why he believes label declaration of the marker should be subject to this exemption; and

(2) The person requesting the exemption has received from the Commissioner of Food and Drugs a finding that the marker is harmless and that the exemption has been granted.

(h) Wrapped fish fillets of nonuniform weight intended to be unpacked and marked with the correct weight at or before the point of retail sale in an establishment other than that where originally packed shall be exempt from the requirement of section 403(e)(2) of the act during introduction and movement in interstate commerce and while held for sale prior to weighing and marking:

(1) *Provided*, That (i) The outside container bears a label declaration of the total net weight; and

(ii) The individual packages bear a conspicuous statement "To be weighed at or before time of sale" and a correct statement setting forth the weight of the wrapper;

(2) *Provided further*, That it is the practice of the retail establishment to weigh and mark the individual packages with a correct net-weight statement prior to or at the point of retail sale. A statement of the weight of the wrapper shall be set forth so as to be readily read and understood, using such term as "wrapper tare—ounce", the blank being filled in with the correct average weight of the wrapper used.

(3) The act of delivering the wrapped fish fillets during the retail sale without the correct net-weight statement shall be deemed an act which results in the product's being misbranded while held for sale. Nothing in this paragraph shall be construed as requiring net-weight statements for wrapped fish fillets delivered into institutional trade provided the outside container bears the required information.

(i) Wrapped clusters (consumer units) of bananas of nonuniform weight intended to be unpacked from a master carton or container and weighed at or before the point of retail sale in an establishment other than that where originally packed shall be exempt from the requirements of section 403(e)(2) of the act during introduction and movement in interstate commerce and while held for sale prior to weighing:

(1) *Provided*, That (i) The master carton or container bears a label declaration of the total net weight; and

(ii) The individual packages bear a conspicuous statement "To be weighed at or before the time of sale" and a correct statement setting forth the weight of the wrapper; using such term as "wrapper tare ——— ounce", the blank being filled in with the correct average weight of the wrapper used;

(2) *Provided further*, That it is the practice of the retail establishment to weigh the individual packages either prior to or at the time of retail sale.

(3) The act of delivering the wrapped clusters (consumer units) during the retail sale without an accurate net weight statement or alternatively without weighing at the time of sale shall be deemed an act which results in the product's being misbranded while held for sale. Nothing in this paragraph shall be construed as requiring net-weight statements for clusters (consumer units) delivered into institutional trade, provided that the master container or carton bears the required information.

§ 101.103 Petitions requesting exemptions from or special requirements for label declaration of ingredients.

The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition pursuant to Part 2 of this chapter may issue a proposal to amend § 101.4 to specify the manner in which an ingredient(s) shall be declared, i.e., by specific or class name, or § 101.100 to exempt an ingredient(s) from the requirements for label declaration.

§ 101.105 Declaration of net quantity of contents when exempt.

(a) The principal display panel of a food in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a

combination of numerical count and weight or measure. The statement shall be in terms of fluid measure if the food is liquid, or in terms of weight if the food is solid, semisolid, or viscous, or a mixture of solid and liquid; except that such statement may be in terms of dry measure if the food is a fresh fruit, fresh vegetable, or other dry commodity that is customarily sold by dry measure. If there is a firmly established general consumer usage and trade custom of declaring the contents of a liquid by weight, or a solid, semisolid, or viscous product by fluid measure, it may be used. Whenever the Commissioner determines that an existing practice of declaring net quantity of contents by weight, measure, numerical count, or a combination in the case of a specific packaged food does not facilitate value comparisons by consumers and offers opportunity for consumer confusion, he will by regulation designate the appropriate term or terms to be used for such commodity.

(b) (1) Statements of weight shall be in terms of avoirdupois pound and ounce.

(2) Statements of fluid measure shall be in terms of the U.S. gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof, and shall:

(i) In the case of frozen food that is sold and consumed in a frozen state, express the volume at the frozen temperature.

(ii) In the case of refrigerated food that is sold in the refrigerated state, express the volume at 40° F (4° C).

(iii) In the case of other foods, express the volume at 68° F (20° C).

(3) Statements of dry measure shall be in terms of the U.S. bushel of 2,150.42 cubic inches and peck, dry quart, and dry pint subdivisions thereof.

(c) When the declaration of quantity of contents by numerical count does not give adequate information as to the quantity of food in the package, it shall be combined with such statement of weight, measure, or size of the individual units of the foods as will provide such information.

(d) The declaration may contain common or decimal fractions. A common fraction shall be in terms of halves, quarters, eighths, sixteenths, or thirty-seconds; except that if there exists a firmly established general consumer usage and trade custom of employing different common fractions in the net quantity declaration of a particular commodity, they may be employed. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places. A statement that includes small fractions of an ounce shall be deemed to permit smaller variations than one which does not include such fractions.

(e) The declaration shall be located on the principal display panel of the label, and with respect to packages bearing alternate principal panels it shall be duplicated on each principal display panel.

(f) The declaration shall appear as a distinct item on the principal display panel, shall be separated (by at least a space equal to the height of the lettering used in the declaration) from other printed label information appearing above or below the declaration and (by at least a space equal to twice the width of the letter "N" of the style of type used in the quantity of contents statement) from other printed label information appearing to the left or right of the declaration. It shall not include any term qualifying a unit of weight, measure, or count (such as "jumbo quart" and "full gallon") that tends to exaggerate the amount of the food in the container. It shall be placed on the principal display panel within the bottom 30 percent of the area of the label panel in lines generally parallel to the base on which the package rests as it is designed to be displayed: *Provided*, That on packages having a principal display panel of 5 square inches or less, the requirement for placement within the bottom 30 percent of the area of the label panel shall not apply when the declaration of net quantity of contents meets the other requirements of this part.

(g) The declaration shall accurately reveal the quantity of food in the package exclusive of wrappers and other material packed therewith: *Provided*, That in the case of foods packed in containers designed to deliver the food under pressure, the declaration shall state the net quantity of the contents that will be expelled when the instructions for use as shown on the container are followed. The propellant is included in the net quantity declaration.

(h) The declaration shall appear in conspicuous and easily legible boldface print or type in distinct contrast (by typography, layout, color, embossing, or molding) to other matter on the package; except that a declaration of net quantity blown, embossed, or molded on a glass or plastic surface is permissible when all label information is so formed on the surface. Requirements of conspicuousness and legibility shall include the specifications that:

(1) The ratio of height to width (of the letter) shall not exceed a differential of 3 units to 1 unit (no more than 3 times as high as it is wide).

(2) Letter heights pertain to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter "o" or its equivalent that shall meet the minimum standards.

(3) When fractions are used, each component numeral shall meet one-half the minimum height standards.

(i) The declaration shall be in letters and numerals in a type size established in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following type specifications:

(1) Not less than one-sixteenth inch in height on packages the principal display panel of which has an area of 5 square inches or less.

(2) Not less than one-eighth inch in height on packages the principal display panel of which has an area of more than 5 but not more than 25 square inches.

(3) Not less than three-sixteenths inch in height on packages the principal display panel of which has an area of more than 25 but not more than 100 square inches.

(4) Not less than one-fourth inch in height on packages the principal display panel of which has an area of more than 100 square inches, except not less than ½ inch in height if the area is more than 400 square inches.

Where the declaration is blown, embossed, or molded on a glass or plastic surface rather than by printing, typing, or coloring, the lettering sizes specified in paragraph (h) (1) through (4) of this section shall be increased by one-sixteenth of an inch.

(j) On packages containing less than 4 pounds or 1 gallon and labeled in terms of weight or fluid measure:

(1) The declaration shall be expressed both in ounces, with identification by weight or by liquid measure and, if applicable (1 pound or 1 pint or more) followed in parentheses by a declaration in pounds for weight units, with any remainder in terms of ounces or common or decimal fractions of the pound (see examples set forth in paragraph (m) (1) and (2) of this section), or in the case of liquid measure, in the largest whole units (quarts, quarts and pints, or pints, as appropriate) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart (see examples in paragraph (m) (3) and (4) of this section).

(2) If the net quantity of contents declaration appears on a random package, that is a package which is one of a lot, shipment, or delivery of packages of the same consumer commodity with varying weights and with no fixed weight pattern, it may, when the net weight exceeds 1 pound, be expressed in terms of pounds and decimal fractions of the pound carried out to not more than two decimal places. When the net weight does not exceed 1 pound, the declaration on the random package may be in decimal fractions of the pound in lieu of ounces (see example in paragraph (m) (5) of this section).

(3) The declaration may appear in more than one line. The term "net weight" shall be used when stating the net quantity of contents in terms of weight. Use of the terms "net" or "net contents" in terms of fluid measure or numerical count is optional. It is sufficient to distinguish avoirdupois ounce from fluid ounce through association of terms; for example, "Net wt. 6 oz" or "6 oz Net wt." and "6 fl oz" or "Net contents 6 fl oz".

(k) On packages containing 4 pounds or 1 gallon or more and labeled in terms of weight or fluid measure, the declaration shall be expressed in pounds for weight units with any remainder in terms of ounces or common or decimal fraction of the pound, or in the case of fluid measure, it shall be expressed in the largest whole unit (gallons followed by common or decimal fraction of a gal-

lon or by the next smaller whole unit or units (quarts, or quarts and pints)) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart (see paragraph (m)(6) of this section).

(l) [Reserved.]

(m) Examples:

(1) A declaration of 1½ pounds weight shall be expressed as "Net Wt. 24 oz (1 lb 8 oz)," "Net Wt. 24 oz (1½ lb)," or "Net Wt. 24 oz (1.5 lb)".

(2) A declaration of three-fourths pound avoirdupois weight shall be expressed as "Net Wt. 12 oz".

(3) A declaration of 1 quart liquid measure shall be expressed as "Net 32 fl oz (1 qt)".

(4) A declaration of 1¾ quarts liquid measure shall be expressed as "Net contents 56 fluid ounces (1 quart 1½ pints)" or as "Net 56 fluid oz (1 qt 1 pt 8 oz)", but not in terms of quart and ounce such as "Net 56 fluid oz (1 quart 24 ounces)".

(5) On a random package, declaration of three-fourths pound avoirdupois may be expressed as "Net Wt. .75 lb".

(6) A declaration of 2½ gallons liquid measure shall be expressed as "Net contents 2½ gallons," "Net contents 2.5 gallons," or "Net contents 2 gallons 2 quarts" and not as "2 gallons 4 pints".

(n) For quantities, the following abbreviations and none other may be employed (periods and plural forms are optional):

weight wt	pint pt
ounce oz	quart qt
pound lb	fluid fl
gallon gal	

(o) Nothing in this section shall prohibit supplemental statements at locations other than the principal display panel(s) describing in nondeceptive terms the net quantity of contents; provided, that such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the food contained in the package; for example, "jumbo quart" and "full gallon". Dual or combination declarations of net quantity of contents as provided for in paragraphs (a), (c), and (j) of this section (for example, a combination of net weight plus numerical count, net contents plus dilution directions of a concentrate, etc.) are not regarded as supplemental net quantity statements and may be located on the principal display panel.

(p) A separate statement of the net quantity of contents in terms of the metric system is not regarded as a supplemental statement and an accurate statement of the net quantity of contents in terms of the metric system of weight or measure may also appear on the principal display panel or on other panels.

(q) The declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large.

(r) The declaration of net quantity of contents on pickles and pickle products, including relishes but excluding one or two whole pickles in clear plastic bags which may be declared by count, shall be expressed in terms of the U.S. gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof.

(s) On a multiunit retail package, a statement of the quantity of contents shall appear on the outside of the package and shall include the number of individual units, the quantity of each individual unit, and, in parentheses, the total quantity of contents of the multiunit package in terms of avoirdupois or fluid ounces, except that such declaration of total quantity need not be followed by an additional parenthetical declaration in terms of the largest whole units and subdivisions thereof, as required by paragraph (j)(1) of this section. A multiunit retail package may thus be properly labeled: "6–16 oz bottles—(96 fl oz)" or "3–16 oz cans—(net wt. 48 oz)". For the purposes of this section, "multiunit retail package" means a package containing two or more individually packaged units of the identical commodity and in the same quantity, intended to be sold as part of the multiunit retail package but capable of being individually sold in full compliance with all requirements of the regulations in this part. Open multiunit retail packages that do not obscure the number of units nor prevent examination of the labeling on each of the individual units are not subject to this paragraph if the labeling of each individual unit complies with the requirements of paragraphs (f) and (i) of this section. The provisions of this section do not apply to that butter or margarine covered by the exemptions in § 1.1c(a)(10) and (11).

(t) Where the declaration of net quantity of contents is in terms of net weight and/or drained weight or volume and does not accurately reflect the actual quantity of the contents or the product falls below the applicable standard of fill of container because of equipment malfunction or otherwise unintentional product variation, and the label conforms in all other respects to the requirements of this chapter (except the requirement that food falling below the applicable standard of fill of container shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter), the mislabeled food product, including any food product that fails to bear the general statement of substandard fill specified in § 130.14(b) of this chapter, may be sold by the manufacturer or processor directly to institutions operated by Federal, State or local governments (schools, prisons, hospitals, etc.): *Provided*, That:

(1) The purchaser shall sign a statement at the time of sale stating that he is aware that the product is mislabeled to include acknowledgment of the nature and extent of the mislabeling, (e.g., "Actual net weight may be as low as ____% below labeled quantity") and that any subsequent distribution by him of said product except for his own institutional use is unlawful. This statement shall be kept on file at the principal place of business of the manufacturer or processor for 2 years subsequent to the date of shipment of the product and shall be available to the Food and Drug Administration upon request.

(2) The product shall be labeled on the outside of its shipping container with the statement(s):

(i) When the variation concerns net weight and/or drained weight or volume, "Product Mislabeled. Actual net weight (drained weight or volume where appropriate) may be as low as ____% below labeled quantity. This Product Not for Retail Distribution", the blank to be filled in with the maximum percentage variance between the labeled and actual weight or volume of contents of the individual packages in the shipping container, and

(ii) When the variation is in regard to a fill of container standard, "Product Mislabeled. Actual fill may be as low as __% below standard of fill. This Product Not for Retail Distribution".

(3) The statements required by paragraph (t)(2) (i) and (ii) of this section, which may be consolidated where appropriate, shall appear prominently and conspicuously as compared to other printed matter on the shipping container and in boldface print or type on a clear, contrasting background in order to render them likely to be read and understood by the purchaser under ordinary conditions of purchase.

(Sec. 5(a), 80 Stat. 1296 (15 U.S.C. 1454).)

PART 102—COMMON OR USUAL NAME FOR NONSTANDARDIZED FOODS

Subpart A—General Provisions

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102.47 Bonito.
102.49 Fried clams made from minced clams.
102.50 Crabmeat.
102.54 Seafood cocktails.
102.55 Nonstandardized breaded composite shrimp units.
102.57 Greenland turbot (*Reinhardtius hippoglossoides*).

AUTHORITY: Secs. 201(n), 403, 701(a), 52 Stat. 1041 as amended, 1047–1048 as amended, 1055 (21 U.S.C. 321(n), 343, 371(a)).

Subpart A—General Provisions

§ 102.5 General principles.

(a) The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods.

(b) The common or usual name of a food shall include the percentage(s) of any characterizing ingredient(s) or component(s) when the proportion of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case. The following requirements shall apply unless modified by a specific regulation in Subpart B of this part.

(1) The percentage of a characterizing ingredient or component shall be declared on the basis of its quantity in the finished product (i.e., weight/weight in the case of solids, or volume/volume in the case of liquids).

(2) The percentage of a characterizing ingredient or component shall be declared by the words "containing (or contains) ____ percent (or %) ____" or "____ percent (or %) ____" with the first blank filled in with the percentage expressed as a whole number not greater than the actual percentage of the ingredient or component named and the second blank filled in with the common or usual name of the ingredient or component. The word "containing" (or "contains"), when used, shall appear on a line immediately below the part of the common or usual name of the food required by paragraph (a) of this section. For each characterizing ingredient or component, the words "____ percent (or %) ____" shall appear following or directly below the word "containing" (or contains), or directly below the part of the common or usual name of the food required by paragraph (a) of this section when the word "containing" (or contains) is not used, in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

(i) Not less than one-sixteenth inch in height on packages having a principal display panel with an area of 5 square inches or less and not less than one-eighth inch in height if the area of the principal display panel is greater than 5 square inches; or

(ii) Not less than one-half the height of the largest type appearing in the part of the common or usual name of the food required by paragraph (a) of this section.

(c) The common or usual name of a food shall include a statement of the presence or absence of any characterizing ingredient(s) or component(s) and/or the need for the user to add any characterizing ingredient(s) or component(s) when the presence or absence of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present when it is not, and consumers may otherwise be misled about the presence or absence of the ingredient(s) or component(s) in the food. The following requirements shall apply unless modified by a specific regulation in Subpart B of this part.

(1) The presence or absence of a characterizing ingredient or component shall be declared by the words "containing (or contains) _____" or "containing (or contains) no _____" or "no _____" or "does not contain _____", with the blank being filled in with the common or usual name of the ingredient or component.

(2) The need for the user of a food to add any characterizing ingredient(s) or component(s) shall be declared by an appropriate informative statement.

(3) The statement(s) required under paragraph (c) (1) and/or (2) of this section shall appear following or directly below the part of the common or usual name of the food required by paragraphs (a) and (b) of this section, in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the alternatives established under paragraph (b) (2) (i) and (ii) of this section.

(d) A common or usual name of a food may be established by common usage or by establishment of a regulation in Subpart B of this part, in Part 104 of this chapter, in a standard of identity, or in other regulations in this chapter.

§ 102.19 Petitions.

(a) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to issue, amend, or revoke, under this part, a regulation prescribing a common or usual name for a food, pursuant to Part 2 of this chapter.

(b) If the principal display panel of a food for which a common or usual name regulation is established is too small to accommodate all mandatory requirements, the Commissioner may establish by regulation an acceptable alternative, e.g., a smaller type size. A petition requesting such a regulation, which would amend the applicable regulation, shall be submitted pursuant to Part 2 of this chapter.

Subpart B—Requirements for Specific Nonstandardized Foods

§ 102.26 Frozen "heat and serve" dinners.

(a) A frozen "heat and serve" dinner:

(1) Shall contain at least three components, one of which shall be a significant source of protein and each of which shall consist of one or more of the following: meat, poultry, fish, cheese, eggs, vegetables, fruit, potatoes, rice, or other cereal based products (other than bread or rolls).

(2) May also contain other servings of food (e.g., soup, bread or rolls, beverage, dessert).

(b) The common or usual name of the food consists of all of the following:

(1) The phrase "frozen 'heat and serve' dinner," except that the name of the predominant characterizing ingredient or other appropriately descriptive term may immediately precede the word "dinner" (e.g., "frozen chicken dinner" or "frozen heat and serve beef dinner"). The words "heat and serve" are optional. The word "frozen" is also optional, provided that the words "Keep Frozen" or the equivalent are prominently and conspicuously placed on the principal display panel in type size not less than that specified in § 102.5(b) (2) (i).

(2) The phrase "containing (or contains) ————" the blank to be filled in with an accurate description of each of the three or more dish components listed in paragraph (a) (1) of this section in their order of descending predominance by weight (e.g., ham, mashed potatoes, and peas), followed by any of the other servings specified in paragraph (a) (2) of this section contained in the package (e.g., onion soup, enriched white bread, and artificially flavored vanilla pudding) in their order of descending predominance by weight. This part of the name shall by placed immediately following or directly below the part specified in paragraph (b) (1) of this section in the manner set forth in § 102.5(c) (3). The words "contains" or "containing" are optional.

(3) If the labeling implies that the package contains other foods and these foods are not present in the package, e.g., if a vignette on the package depicts a "serving suggestion" which includes any foods not present in the package, the principal display panel shall bear a statement that such foods are not present, in type size not less than that specified in § 102.5(b) (2) (i).

§ 102.28 Foods packaged for use in the preparation of "main dishes" or "dinners."

(a) The common or usual name of a packaged food which is represented on the principal display panel by word or vignette to be used in the preparation of a "main dish", "dinner", or other such food serving, and to which some other important characterizing ingredient(s) or component(s) not present in the package must be added, consists of all the following:

(1) The common or usual name of each important ingredient or component in the package, in descending order of predominance by weight (e.g., "noodles and tomato sauce").

(2) An appropriate informative statement identifying the food to be prepared by use of the package contents (e.g., "for preparation of chicken casserole").

(3) An appropriate informative statement that additional characterizing ingredient(s) or component(s) must be added and which names the additional characterizing ingredient(s) or component(s) (e.g., "you must add _____ to complete the recipe," the blank to be filled in with the name(s) of the important characterizing ingredient(s) or component(s) that must be added).

(b) The labeling required by paragraph (a) of this section shall appear on the principal display panel.

(1) No word in the statement required by paragraph (a)(2) of this section may appear on the principal display panel more conspicuously or in larger type than the smallest and least conspicuous type employed on the panel for any word, phrase or statement within the scope of paragraph (a)(1) of this section.

(2) Every word in the statement required by paragraph (a)(3) of this section shall appear on the principal display panel in easily legible bold face print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

(i) Not less than one-sixteenth inch in height on packages having a principal display panel with an area of 5 square inches or less and not less than one-eighth inch in height if the area of the principal display panel is greater than 5 square inches; or

(ii) Not less than one-half the height of the largest type appearing in the part of the common or usual name of the food required by paragraph (a)(1) and (2) of this section.

(c) Any vignette which shows any food or characterizing ingredient(s) or component(s) not included in the package shall be accompanied either by the statement required by paragraph (a)(3) of this section or by a separate statement specifying the food or characterizing ingredient(s) or component(s) shown in the vignette but not included in the package.

(d) If the statement specified in paragraph (a)(2) of this section is used on any panel in addition to the principal display panel as a product identification statement, the complete common or usual name shall appear on such panel in the manner specified in paragraph (b) of this section.

(e) When a brand name or other prominent product designation contains a word or words that includes or suggests an important characterizing ingredient(s) or component(s) that must be added, or otherwise states or implies that the package contains a complete main dish, dinner, or other food serving, the part of the common or usual name of the food required by paragraph (a)(3) of this section shall appear in direct conjunction with such brand name or other designation and in type size not less than one-half the height of the largest type appearing in such brand name or other designation.

§ 102.30 Noncarbonated beverage products containing no fruit or vegetable juice.

The common or usual name of noncarbonated beverage products (including a concentrated, dehydrated, powdered, or other counterpart) containing no fruit or vegetable juice shall include the following:

(a) A descriptive name for the product meeting the requirements of § 102.5(a); and

(b) When the labeling or the color, and flavor of the beverage represents, suggests, or implies that any fruit or vegetable juice may be present (e.g., the product label bears the name or a variation of the name or any pictorial representation of any fruit or vegetable, or the product contains color and flavor which give the beverage the appearance and taste of containing a fruit or vegetable juice) the statement "Containing (or contains) no _____ juice", or "no _____ juice", or "does not contain _____ juice", the blank to be filled in with the name of the fruit(s) or vegetable(s) represented, suggested, or implied, in the manner set forth in § 102.5(c). If a nonspecific fruit or vegetable juice content is represented, suggested, or implied, the blank shall be filled in with the word "fruit" or "vegetable" as applicable.

§ 102.32 Diluted orange juice beverages.

(a) The common or usual name of a noncarbonated beverage containing less than 100 percent and more than 0 percent orange juice shall be as follows:

(1) A descriptive name for the product meeting the requirements of § 102.5(a) (e.g., diluted orange juice beverage or another descriptive phrase) and

(2) A statement of the percent of orange juice contained in the product in the manner set forth in § 102.5(b)(2). The percent of orange juice shall be declared in 5-percent increments, expressed as a multiple of five not greater than the actual percentage of orange juice in the product, except that the percent of orange juice in products containing more than 0 percent but less than 5-percent orange juice shall be declared in the statement as "less than 5" percent.

(b) The percent of orange juice in the product shall be determined on the basis of the orange juice having an equivalent single strength of 11.8 percent orange juice soluble solids.

§ 102.37 Mixtures of edible fat or oil and olive oil.

The common or usual name of a mixture of edible fats and oils containing less than 100 percent and more than 0 percent olive oil shall be as follows:

(a) A descriptive name for the product meeting the requirements of § 102.5(a), e.g., "cottonseed oil and olive oil" or another descriptive phrase, and

(b) When the label bears any representation, other than in the ingredient listing, of the presence of olive oil in the mixture, the descriptive name shall be followed by a statement of the percentage of olive oil contained in the product in the manner set forth in § 102.5(b)(2).

§ 102.39 Onion rings made from diced onion.

(a) The common or usual name of the food product that resembles and is of the same composition as onion rings, except that it is composed of comminuted onions, shall be as follows:

(1) When the product is composed of dehydrated onions, the name shall be "onion rings made from dried diced onions."

(2) When the product is composed of any form of onion other than dehydrated, the name shall be "onion rings made from diced onions."

(b) The words "made from dried diced onions" or "made from diced onions" shall immediately follow or appear on a line(s) immediately below the words "onion rings" in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

(1) Not less than one-sixteenth inch in height on packages having a principal display panel with an area of 5 square inches or less and not less than one-eighth inch in height if the area of the principal display panel is greater than 5 square inches; or

(2) Not less than one-half the height of the largest type used in the words "onion rings."

§ 102.41 Potato chips made from dried potatoes.

(a) The common or usual name of the food product that resembles and is of the same composition as potato chips, except that it is composed of dehydrated potatoes (buds, flakes, granules, or other form), shall be "potato chips made from dried potatoes."

(b) The words "made from dried potatoes" shall immediately follow or appear on a line(s) immediately below the words "potato chips" in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

(1) Not less than one-sixteenth inch in height on packages having a principal display panel with an area of 5 square inches or less and not less than one-eighth inch in height if the area of the principal display panel is greater than 5 square inches; or

(2) Not less than one-half the height of the largest type used in the words "potato chips."

§ 102.45 Fish sticks or portions made from minced fish.

(a) The common or usual name of the food product that resembles and is of the same composition as fish sticks or fish portions, except that it is composed

of comminuted fish flesh, shall be "fish _____ made from minced fish," the blank to be filled in with the word "sticks" or "portions" as the case may be.

(b) The words "made from minced fish" shall immediately follow or appear on a line(s) immediately below the words "fish _____" in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

(1) Not less than one-sixteenth inch in height on packages having a principal display panel with an area of 5 square inches or less and not less than one-eighth inch in height if the area of the principal display panel is greater than 5 square inches; or

(2) Not less than one-half the height of the largest type used in the words "fish _____"

§ 102.47 Bonito.

"Bonito" or "bonito fish" is the common or usual name of the food fish *Sardi chilensis* and *Sardi velox*.

§ 102.49 Fried clams made from minced clams.

(a) The common or usual name of the food product that resembles and is of the same composition as fried clams, except that it is composed of comminuted clams, shall be "fried clams made from minced clams."

(b) The words "made from minced clams" shall immediately follow or appear on a line(s) immediately below the words "fried clams" and in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

(1) Not less than one-sixteenth inch in height on packages having a principal display panel with an area of 5 square inches or less and not less than one-eighth inch in height if the area of the principal display panel is greater than 5 square inches; or

(2) Not less than one-half the height of the largest type used in the words "fried clams."

§ 102.50 Crabmeat.

The common or usual name of crabmeat derived from each of the following designated species of crabs shall be as follows:

Scientific name of crab	*Common or usual name of crabmeat*
Paralithodes camtschatica and *Paralithodes platypus*.	King crabmeat.
*Paralithodes brevipes*___	King crabmeat or Hanasaki crabmeat.
*Erimacrus isenbeckii*___	Korean variety crabmeat or Kegani crabmeat.
Chionoecetes opilio, Chionoecetes tanneri, Chionoecetes bairdii, and *Chionoecetes angulatus*.	Snow crabmeat.

§ 102.54 Seafood cocktails.

The common or usual name of a seafood cocktail in package form fabricated with one or more seafood ingredients shall be:

(a) When the cocktail contains only one seafood ingredient, the name of the seafood ingredient followed by the word "cocktail" (e.g., shrimp cocktail, crabmeat cocktail) and a statement of the percentage by weight of that seafood ingredient in the product in the manner set forth in § 102.5(b).

(b) When the cocktail contains more than one seafood ingredient, the term "seafood cocktail" and a statement of the percentage by weight of each seafood ingredient in the product in the manner set forth in § 102.5(b).

NOTE: Section 102.54 (formerly § 102.5) was stayed in its entirety at 40 FR 26267, June 23, 1975.

§ 102.55 Nonstandardized breaded composite shrimp units.

(a) The common on usual name of the food product that conforms to the definition and standard of identity described by § 161.175(c)(6) of this chapter, except that the food is made from comminuted shrimp and is not in raw frozen form, shall be "_____ made from minced shrimp," the blank to be filled in with the words "breaded shrimp sticks" or "breaded shrimp cutlets" depending upon the shape of the product, or if prepared in a shape other than that of sticks or cutlets "breaded shrimp _____ made from minced shrimp," the blank to be filled by a word or phrase that accurately describes the shape and that is not misleading.

(b) The words "made from minced shrimp" shall immediately follow or appear on a line(s) immediately below the other words required by this section in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

(1) Not less than one-sixteenth inch in height on packages having a principal display panel with an area of 5 square inches or less and no less than one-eighth inch in height if the area of the principal display panel is greater than 5 square inches; or

(2) Not less than one-half the height of the largest type used in the words "breaded shrimp sticks" or the other comparable words required by this section.

§ 102.57 Greenland turbot (*Reinhardtius hippoglossoides*).

"Greenland turbot" is the common or usual name of the food fish *Reinhardtius hippoglossoides*, a species of *Pleuronectidae* right-eye flounders. The term "halibut" may be associated only with Atlantic halibut (*Hippoglossus hippoglossus*) or Pacific halibut (*Hippoglossus stenolepis*).

PART 103—QUALITY STANDARDS FOR FOODS WITH NO IDENTITY STANDARDS

Subpart A—General Provisions

Sec.
103.3 Definitions.
103.5 General principles.

Subpart B—Standards of Quality

Sec.
103.23 Frozen ready-to-eat banana, coconut, chocolate, or lemon cream-type pies.
103.29 Food grade gelatin.
103.35 Bottled water.

AUTHORITY: Secs. 401, 403, 701, 52 Stat. 1046–1048 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 341, 343, 371) unless otherwise noted.

Subpart A—General Provisions

§ 103.3 Definitions.

(a) A "lot" is:

(1) For purposes of determining quality factors related to manufacture, processing, or packing, a collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible and usually designated by a common container code or marking, or in the absence of any common container code or marking, a day's production.

(2) For purposes of determining quality factors related to distribution and storage, a collection of primary containers or units transported, stored, or held under conditions as nearly uniform as possible.

(b) A "sample" consists of 10 subsamples (consumer units), taken one from each of 10 different randomly chosen shipping cases to be representative of a given lot, unless otherwise specified in a specific quality standard in this part.

(c) An "analytical unit" is the portion(s) of food taken from a subsample of a sample for the purpose of analysis.

§ 103.5 General principles.

(a) The quality of a food depends upon numerous characteristics including but not limited to the levels of microorganisms and such physical factors as turbidity, color, flavor, and odor. Such characteristics are indicative of the quality of the raw materials and ingredients, the degree of quality control used in manufacture, processing, and packing, and the conditions of distribution and storage. The diversity of raw materials, food processing, and distribution practices, as well as the variation in quality factors important to consumers, requires that individual standards of quality be established for different types of food.

(b)(1) The label of a food that fails to meet the requirements of an applicable standard of quality promulgated pursuant to this part shall bear the general statement of substandard quality specified in § 130.14(a) of this chapter in the manner and form therein specified; but in lieu of such general statement of substandard quality, the label may bear the alternative statement, "Below Standard in Quality—_____", the blank to be filled in with whichever of the following are applicable:

(i) "Contains Excessive Bacteria".

(ii) "Excessively Turbid".

(iii) "Abnormal Color".

(iv) The phrase specified in the applicable standard of quality to describe any other quality deviation.

(2) The statement of substandard quality shall appear on the principal display panel or panels and shall immedi-

ately and conspicuously precede or follow, without intervening written, printed or graphic matter, the name of the food.

(c) Product descriptions included in a standard of quality promulgated pursuant to this part are intended only to designate the class of foods to which the standards apply, and are not standards of identity for the products involved. Should a standard of identity later be established for any of these foods, the standard of quality will be recodified to appear in the same part of the regulations.

(d) The food characteristics included in a standard of quality published in this part relate only to the quality of the food and not to compliance with any of the adulteration provision of section 402 of the act. Compliance with a standard of quality promulgated pursuant to this part does not excuse failure to observe either the requirement of section 402(a)(4) of the act that food may not be prepared, packed, or held under insanitary conditions, or the provisions of Part 110 of this chapter requiring that food manufacturers must observe current food manufacturing practices. For example, evidence obtained through factory inspection indicating such a violation renders the food unlawful, even though the food contains levels of microorganisms lower than those prescribed by an applicable standard.

(e) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may establish amend, or repeal, under Subpart B of this part, a regulation prescribing a standard of quality for a food pursuant to Part 2 of this chapter.

Subpart B—Standards of Quality

§ 103.23 Frozen ready-to-eat banana, coconut, chocolate, or lemon cream-type pies.

(a) For the purposes of this section a frozen ready-to-eat banana, coconut, chocolate, or lemon cream-type pie is a frozen ready-to-eat pie that is labeled as and/or has the physical and compositional characteristics of a cream-type pie, including but not limited to semi-solid filling and/or topping, and contains flavoring and/or fruit ingredients corresponding to the banana, coconut, chocolate, or lemon flavor representation made for such pie. It is made with or without a crust.

(b) A sample of a frozen ready-to-eat banana, coconut, chocolate, or lemon cream-type pie, as defined in § 103.3(b) when examined by the methods described in sections 41.015 and 41.016 of the "Official Methods of Analysis of the Association of Official Analytical Chemists" 11th Ed. (1970),[3] shall meet standards of microbiological quality as follows:

(1) Aerobic plate count (geometric mean) ≤50,000 per gram.

(2) Coliform count (geometric mean) ≤50 per gram, MPN.

(c) If the microbiological quality of the cream-type pies described in paragraph (a) of this section falls below the standard prescribed by paragraph (b) of this section, the label shall bear the statement of substandard quality specified in § 103.5(b)(1)(i).

§ 103.29 Food grade gelatin.

(a) For the purposes of this section food grade gelatin is the high quality edible ground product that is labeled as and/or has the physical and compositional characteristics of gelatin. It is extracted from animal bones and tissues in accordance with current good manufacturing practices. In hot solution it does not have a foreign odor, is clear and of light color.

(b) A sample of food grade gelatin, as defined in § 103.3(b), when examined in accordance with the methods described in sections 41.015 and 41.016 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970),[3] shall meet standards of microbiological quality as follows:

(1) Aerobic plate count (geometric mean) ≤3,000 per gram.

(2) Coliform count (geometric mean) ≤10 per gram, MPN. In the preparation for examination of an analytical unit, as defined in § 103.3(c), 10 grams are weighed out aseptically into a 90 milliliter sterile water blank containing glass beads held at 45° C, with intermittent shaking for not more than 15 minutes.

(c) If the microbiological quality of gelatin falls below the standard as prescribed by paragraph (b) of this section, the label shall bear the statement of substandard quality specified in § 103.5(b)(1)(i).

§ 103.35 Bottled water.

(a) *Definition.* "Bottled water" is defined as water that is sealed in bottles or other containers and intended for human consumption. Bottled water does not include mineral water or any food defined in § 165.175 of this chapter.

(b) *Microbiological quality.* Bottled water shall, when a sample consisting of analytical units of equal volume is examined by the methods described in Part 400 of "Standard Methods for the Examination of Water and Wastewater," 13th Ed., 1971, American Public Health Association,[4] meet standards of microbiological quality as follows:

(1) *Multiple-tube fermentation method.* Not more than one of the analytical units in the sample shall have a most probable number (MPN) of 2.2 or more coliform organisms per 100 milliliters and no analytical unit shall have a MPN of 9.2 or more coliform organisms per 100 milliliters, or:

(2) *Membrane filter method.* Not more than one of the analytical units in the sample shall have 4.0 or more coliform organisms per 100 milliliters and the arithmetic mean of the coliform density of the sample shall not exceed one coliform organism per 100 milliliters.

(c) *Physical quality.* Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the method described in Part 100 of the 13th Ed., 1971, of "Standard Methods for the Examination of Water and Wastewater," American Public Health Association,[4] meet standards of physical quality as follows:

(1) The turbidity shall not exceed 5 units.

(2) The color shall not exceed 15 units.

(3) The odor shall not exceed threshold odor No. 3.

(d)(1) *Chemical quality.* Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in Part 100 of the 13th Ed., 1971, of "Standard Methods of Examination of Water and Wastewater," American Public Health Association[4], meet standards of chemical quality and shall not contain chemical substances in excess of the following concentrations:

Substance:	*Concentration in milligrams per liter*
Arsenic	0.05
Barium	1.0
Cadmium	0.01
Chloride	250.0
Chromium (Hexavalent)	0.05
Copper	1.0
Cyanide	0.2
Iron	0.3
Lead	0.05
Manganese	0.05
Nitrate	45.0
Phenols	0.001
Selenium	0.01
Silver	0.05
Sulfate	250.0
Total Dissolved Solids	500.0
Zinc	5.0

(2)(i) Bottled water packaged in the United States to which no fluoride is added shall not contain fluoride in excess of the levels in Table 1 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 1

Annual average of maximum daily air temperatures:	*Fluoride concentration in milligrams per liter*
50.0–53.7	2.4
53.8–58.3	2.2
58.4–63.8	2.0
63.9–70.6	1.8
70.7–79.2	1.6
79.3–90.5	1.4

(ii) Imported bottled water to which no fluoride is added shall not contain fluoride in excess of 1.4 milligrams per liter.

(iii) Bottled water packaged in the United States to which fluoride is added shall not contain fluoride in excess of levels in Table 2 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

[3] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

[4] "Standard Methods for the Examination of Water and Wastewater," 13th Ed. 1971, can be obtained from the American Public Health Association, 1015 18th Street NW., Washington, DC 20036.

TABLE 2

Annual average of maximum daily air temperatures:	*Fluoride concentration in milligrams per liter*
50.0–53.7	1.7
53.8–58.3	1.5
58.4–63.8	1.3
63.9–70.6	1.2
70.7–79.2	1.0
79.3–90.5	0.8

(iv) Imported bottled water to which fluoride is added shall not contain fluoride in excess of 0.8 milligram per liter.

(e) *Radiological quality.* Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in Part 300 of the 13th Ed., 1971, of "Standard Methods for the Examination of Water and Wastewater" American Public Health Association,[1] meet standards of radiological quality as follows:

(1) The bottled water shall not contain radioactivity in excess of the following concentrations:

Substance:	*Concentration in microcuries per liter*
Radium-226	3
Strontium-90	10

(2) When it is known that the strontium-90 and alpha emitters are absent, the composite shall not contain a gross beta concentration in excess of 1,000 micromicrocuries per liter.

(f) *Label statements.* Bottled water, the quality of which is below that prescribed by this section, shall be labeled with a statement of substandard quality as follows:

(1) When the microbiological quality of bottled water is below that prescribed by paragraph (b) of this section, the label shall bear the statement of substandard quality specified in § 103.5(b).

(2) When the physical, chemical, and/or radiological quality of bottled water is below that prescribed by paragraphs (c) through (e) respectively of this section, the label shall bear the statement of substandard quality specified in § 103.5(b) except that, as appropriate, instead of or in addition to the words "Contains Excessive Bacteria" the following statement(s) shall be used:

(i) "Excessively Turbid", "Abnormal Color", and/or "Abnormal Odor" if the bottled water fails to meet the requirements of paragraph (c) (1), (2), and/or (3), respectively, of this section.

(ii) "Contains Excessive Chemical Substances", if the bottled water fails to meet any of the requirements of paragraph (d) of this section. The specific chemical(s) may be declared in lieu of the words "Chemical Substances" in the statement "Contains Excessive Chemical Substances". When a specific chemical is declared, that name by which the chemical(s) is designated in paragraph (d) of this section shall be used. Example: "Contains Excessive Copper".

(iii) "Excessively Radioactive" if the bottled water fails to meet the requirements of paragraph (e) of this section.

[1] "Standard Methods for the Examination of Water and Wastewater," 13th Ed. 1971, can be obtained from the American Public Health Association, 1015 18th Street NW., Washington, DC 20036.

(g) *Adulteration.* Bottled water containing a substance at a level considered injurious to health under section 402 (a) (1) of the act is deemed to be adulterated, regardless of whether or not the bottled water bears a label statement of substandard quality prescribed by paragraph (f) of this section.

PART 104—NUTRITIONAL QUALITY GUIDELINES FOR FOODS

Subpart A—General Provisions

Sec.
104.5 General principles.
104.19 Petitions.

Subpart B—[Reserved]

Subpart C—Specific Nutritional Quality Guidelines

104.47 Frozen "heat and serve" dinner.

AUTHORITY: Secs. 201, 403, 701(a), 52 Stat. 1040–1042 as amended, 1047–1048 as amended, 1055 (21 U.S.C. 321, 343, 371(a)) unless otherwise noted.

Subpart A—General Provisions

§ 104.5 General principles.

(a) A nutritional quality guideline prescribes the minimum level or range of nutrient composition (nutritional quality) appropriate for a given class of food.

(b) Labeling for a product which complies with all of the requirements of the nutritional quality guideline established for its class of food may state "This product provides nutrients in amounts appropriate for this class of food as determined by the U.S. Government," except that the words "this product" are optional. This statement, if used, shall be printed on the principal display panel, and may also be printed on the information panel, in letters not larger than twice the size of the minimum type required for the declaration of net quantity of contents by § 101.105 of this chapter. Labeling of noncomplying products may not include any such statement or otherwise represent, suggest, or imply the product as being, in whole or in part, in compliance with a guideline.

(c) A product bearing the statement provided for in paragraph (b) of this section, in addition to meeting the requirements of the applicable nutritional quality guideline, shall comply with the following requirements:

(1) The label of the product shall bear the common or usual name of the food in accordance with the provisions of the guideline and §§ 101.3 and 102.5(a) of this chapter.

(2) The label of the product shall bear nutrition labeling in accordance with §§ 101.2 and 101.9 of this chapter and all other labeling required by applicable sections of Part 101 of this chapter.

(d) No claim or statement may be made on the label or in labeling representing, suggesting, or implying any nutritional or other differences between a product to which nutrient addition has or has not been made in order to meet the guideline, except that a nutrient addition shall be declared in the ingredient statement.

(e) Compliance with a nutrient level specified in a nutritional quality guideline shall be determined by the procedures and requirements established in § 101.9(e) of this chapter.

(f) A product within a class of food for which a nutritional quality guideline has been established and to which has been added a discrete nutrient either for which no minimum nutrient level or nutrient range or other allowance has been established as appropriate in the nutritional quality guideline, or at a level that exceeds any maximum established as appropriate in the guideline, shall be ineligible to bear the guideline statement provided for in paragraph (b) of this section, and such a product shall also be deemed to be misbranded under the act unless the label and all labeling bear the following prominent and conspicuous statement: "The addition of —— to (or "The addition of —— at the level contained in) this product has been determined by the U.S. Government to be unnecessary and inappropriate and does not increase the dietary value of the food," the blank to be filled in with the common or usual name of the nutrient(s) involved.

§ 104.19 Petitions.

The Commissioner of Food and Drugs, on his own initiative, on the advice of the National Academy of Sciences or other experts, or on behalf of any interested person who has submitted a petition, may issue a proposal to issue, amend, or revoke a regulation prescribing a nutritional quality guideline for a class of foods, pursuant to Part 2 of this chapter.

Subpart B—[Reserved]

Subpart C—Specific Nutritional Quality Guidelines

§ 104.47 Frozen "heat and serve" dinner.

(a) A product, for which a common or usual name is established in § 102.26 of this chapter, in order to be eligible to bear the guideline statement set forth at § 104.5(b), shall contain at least the following three components:

(1) One or more sources of protein derived from meat, poultry, fish, cheese, or eggs.

(2) One or more vegetables or vegetable mixtures other than potatoes, rice, or cereal-based product.

(3) Potatoes, rice, or cereal-based product (other than bread or rolls) or another vegetable or vegetable mixture.

(b) The three or more components named in paragraph (a) of this section, including their sauces, gravies, breading, etc.:

(1) Shall contribute not less than the minimum levels of nutrients prescribed in paragraph (d) of this section.

(2) Shall be selected so that one or more of the listed protein sources of paragraph (a)(1) of this section, excluding their sauces, gravies, breading, etc., shall provide not less than 70 percent of the total protein supplied by the components named in paragraph (a) of this section.

(c) If it is necessary to add any nutrient(s) in order to meet the minimum nutrient levels prescribed in paragraph (d) of this section, the addition of each such nutrient may not result in a total nutrient level exceeding 150 percent

of the minimum level prescribed. Nutrients used for such addition shall be biologically available in the final product.

(d) Minimum levels of nutrients for a frozen "heat and serve" dinner are as follows:

Nutrient	Minimum levels for frozen "heat and serve" dinner— For each 100 Calories (kcal) of the total components specified in par. (a)	For the total components specified in par. (a)
Protein, grams	4.60	16.0
Vitamin A, IU	180.00	600.0
Thiamine, mg	.05	.2
Riboflavin, mg	.06	.2
Niacin, mg	.99	3.4
Pantothenic acid, mg	.32	1.1
Vitamin, B_6, mg	.15	.5
Vitamin, B_{12}, mcg	.32	1.1
Iron, mg	.62	2.2

(1) A frozen "heat and serve" dinner prepared from conventional food ingredients listed in paragraph (a) of this section will also contain folic acid, magnesium, iodine, calcium, and zinc. Minimum levels for these nutrients cannot be established at the present time but may be specified as additional data are obtained.

(2) The minimum levels for pantothenic acid, vitamin B–6, and vitamin B–12 are tentative. Final levels will be established when sufficient data are available. Until final levels are established, a product containing less than the tentative levels will not be deemed to be misbranded when labeled in accordance with § 104.5(b).

(3) When technologically practicable, iodized salt shall be used or iodine shall be present at a level equivalent to that which would be present if iodized salt were used in the manufacture of the product.

(4) When technologically practicable, product components and ingredients shall be selected to obtain the desirable calcium to phosphorous ratio of 1:1. Technological addition of phosphates shall be minimized and shall not exceed the amount necessary for the intended effect.

(e) If the product includes servings of food which are not prescribed by paragraph (a) of this section (e.g., soup, bread or rolls, beverage, or dessert), their contribution shall not be considered in determining compliance with the nutrient levels established in paragraph (d) of this section but shall be included in any nutrition labeling.

(f) For the purposes of labeling, an "average serving" shall be one entire frozen "heat and serve" dinner.

PART 105—FOODS FOR SPECIAL DIETARY USE

Subpart A—General Provisions

Sec.

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Subpart C—[Reserved]

Subpart D—Standards of Identity

105.85 Dietary supplements of vitamins and minerals.

AUTHORITY: Secs. 403, 701, 52 Stat. 1047–1048 as amended, 1055–1056 as amended (21 U.S.C. 343, 371) unless otherwise noted.

Subpart A—General Provisions

§ 105.3 Definitions and interpretations.

The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act (hereafter "the act") shall be applicable with the following additions:

(a) *"Special dietary use."* (1) The term "special dietary use" as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:

(i) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium.

(ii) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake. (Rules applicable to the composition and labeling of dietary supplements of vitamins and minerals, including applicable exemptions, are provided by § 105.85.)

(iii) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.

(2) The use of an artificial sweetener in a food, except when specifically and solely used for achieving a physical characteristic in the food which cannot be achieved with sugar or other nutritive sweetener, shall be considered a use for regulation of the intake of calories and available carbohydrate, or for use in the diets of diabetics and is therefore a special dietary use.

(b) *U.S. Recommended Daily Allowances (U.S. RDA's).* (1) The term "U.S. Recommended Daily Allowance (U.S. RDA)" means the following daily amounts of the following vitamins and minerals:

Vitamins and minerals [1]	Unit of measurement	Infants	Children under 4 years of age	Adults and children 4 or more years of age	Pregnant or lactating women
Vitamin A	International units	1,500	2,500	5,000	8,000
Vitamin D	do	400	400	400	400
Vitamin E	do	5	10	30	30
Vitamin C	Milligrams	35	40	60	60
Folic acid	do	.1	.2	.4	.8
Thiamine	do	.5	.7	1.5	1.7
Riboflavin	do	.6	.8	1.7	2.0
Niacin	do	8	9	20	20
Vitamin B_6	do	.4	.7	2.0	2.5
Vitamin B_{12}	Micrograms	2	3	6	8
Biotin	Milligrams	.05	.15	.30	.30
Pantothenic acid	do	3	5	10	10
Calcium	Grams	.6	.8	1.0	1.3
Phosphorus	do	.5	.8	1.0	1.3
Iodine	Micrograms	45	70	150	150
Iron	Milligrams	15	10	18	18
Magnesium	do	70	200	400	450
Copper	do	.6	1.0	2.0	2.0
Zinc	do	5	8	15	15

[1] The following synonyms may be added in parentheses immediately following the name of the vitamin.

Vitamin:	*Synonym*
Vitamin C	Ascorbic acid.
Folic acid	Folacin.
Riboflavin	Vitamin B_2.
Thiamine	Vitamin B_1.

(2) The U.S. Recommended Daily Allowances (U.S. RDA's) have been derived by the Food and Drug Administration from the "Recommended Dietary Allowances," published by the Food and Nutrition Board, National Academy of Sciences/National Research Council, and are subject to amendment as more knowledge on human nutrient requirements becomes available.

(3) For determining the percentage of the U.S. RDA present in a quantity of food, as required by § 105.77(a), the quantitative content of the following vitamins shall be calculated in terms of the following chemically identifiable reference forms:

Reference Form

Vitamin	Name	Empirical formula	Molecular weight
Vitamin C	*L*-Ascorbic acid	$C_6H_8O_6$	176.12
Folic acid	Pteroyl mono-*L*-glutamic acid	$C_{19}H_{19}N_7O_6$	441.41
Thiamine	Thiamine chloride hydrochloride	$C_{12}H_{17}ClN_4OS{\cdot}HCl$	337.28
Riboflavin	Riboflavin	$C_{17}H_{20}N_4O_6$	376.37
Niacin	Nicotinic acid	$C_6H_5NO_2$	123.11
Vitamin B_6	Pyridoxine	$C_8H_{11}NO_3$	169.18
Vitamin B_{12}	Cyanocobalamin	$C_{63}H_{88}CoN_{14}O_{14}P$	1,355.40
Biotin	*D*-Biotin	$C_{10}H_{16}N_2O_3S$	244.31
Pantothenic acid	*D*-Pantothenic acid	$C_9H_{17}NO_5$	219.23

(c) In addition to the nutrients listed in paragraph (b) of this section, other vitamins and minerals recognized as essential or probably essential in human nutrition in their biologically active forms but for which no U.S. RDA's have been established are: vitamin K, choline, and the minerals chlorine, chromium, fluorine, manganese, molybdenum, nickel, potassium, selenium, silicon, sodium, tin, and vanadium.

(d) The term "artificial sweetener" means a sweetening substance not used in normal metabolism as a source of calories.

(e) The term "infant" means a person not more than 12 months of age.

(f) The term "serving" means that reasonable quantity of food suited for or practicable of consumption as part of a meal either by an adult male engaged in light physical activity, or by an infant or child when the article purports or is represented to be for infant feeding or child consumption. A label statement regarding a serving, as used in this part, shall be in terms of a convenient unit of such food or a convenient unit of measure than can be readily understood by purchasers of such food, e.g., a serving may be expressed in terms of slices, cookies, or wafers, or in terms of ounces, fluid ounces, teaspoonfuls, tablespoonfuls, or cupfuls. A teaspoonful shall be considered to mean 5 milliliters (approximately ⅙ fluid ounce) in volume; a tablespoonful shall be considered to mean 15 milliliters (approximately ½ fluid ounce) in volume; and a cupful shall be considered to mean 240 milliliters (approximately 8 fluid ounces) in volume.

(g) The term "diabetic" means a person having diabetes mellitus.

(Secs. 201(n), 401, 403 (a) and (j), 411, 701 (a) and (e), 52 Stat. 1041, 1046–1048, 1055, 70 Stat. 919, 90 Stat. 410–411 (21 U.S.C. 321 (n), 341, 343 (a) and (j), 350, 371 (a) and (e)).)

Subpart B—Label Statements

§ 105.60 Restrictions, placement, false or misleading representations.

(a) If a food purports or is represented to be for any special dietary use, unless covered by other regulations, the principal display panel of its label shall bear a conspicuous statement of the usefulness of the food, limited to a listing of the dietary properties upon which such use is based: *Provided, however,* That if insufficient space is available on the principal display panel, the information panel may be used pursuant to § 101.2 of this chapter, if such use is consistent with § 101.15 of this chapter. Such statement shall show the presence or absence of any substance, any alteration of the quantity or character of any constituent, and any other special dietary property of such food upon which such use is based.

(b) A food which purports or is represented to be a food for special dietary use shall be deemed to be misbranded under sections 201(n) and 403 (a) and (j) of the act if its labeling bears any statement, vignette, or other printed or graphic matter that represents, suggests, or implies:

(1) That the food, because of the presence or absence of certain vitamins and/or minerals, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom, except that the label may state that the food is a source of an essential nutrient and that this nutrient is important for good nutrition and health, and except that provision shall not apply to foods represented for use solely under medical supervision in the dietary management of specific diseases and disorders.

(2) That a balanced diet of ordinary foods cannot supply adequate amounts of nutrients: *Provided,* That representations may be made that it is often impractical to supply the iron requirements of infants, children, and women of childbearing age with a diet of conventional foods.

(3) That the lack of optimum quality of a food, by reason of the soil on which that food is grown, is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(4) That the storage, transportation, processing, or cooking of a food is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(5) That the food has dietary properties when such properties are of no significant value or need in human nutrition. Except as provided in § 105.85(e), ingredients or products such as rutin, other bioflavonoids, paraaminobenzoic acid, and similar substances which have in the past been represented as having nutritional properties but which have not been shown to be essential to human nutrition may not be combined with vitamins and/or minerals, added to food labeled in accordance with this section, or otherwise used or represented in any way which states or implies nutritional benefit. Ingredients or products of this type may be marketed as individual products or mixtures thereof: *Provided,* That the possibility of nutritional, dietary, or therapeutic value is not stated or implied. Examples of false or misleading statements or implications are:

(i) Label statements to the effect that need or usefulness in human nutrition has not been established.

(ii) Label statements which otherwise disclaim nutritional, dietary, or therapeutic value.

(6) That a natural vitamin in a food is superior to an added or synthetic vitamin, or that there is a difference between vitamins naturally present and those that have been added.

(Secs. 201(n), 401, 403 (a) and (j), 411, 701 (a) and (e), 52 Stat. 1041, 1046–1048, 1055, 70 Stat. 919, 90 Stat. 410–411 (21 U.S.C. 321 (n), 341, 343 (a) and (j), 350, 371 (a) and (e)).)

§ 105.62 Hypoallergenic foods.

If a food purports to be or is represented for special dietary use by reason of the decrease or absence of any allergenic property or by reason of being offered as food suitable as a substitute for another food having an allergenic property, the label shall bear:

(a) The common or usual name and the quantity or proportion of each ingredient (including spices, flavoring, and coloring) in case the food is fabricated from two or more ingredients.

(b) A qualification of the name of the food, or the name of each ingredient thereof in case the food is fabricated from two or more ingredients, to reveal clearly the specific plant or animal that is the source of such food or of such ingredient, if such food or such ingredient consists in whole or in part of plant or animal matter and such name does not reveal clearly the specific plant or animal that is such a source.

(c) An informative statement of the nature and effect of any treatment or processing of the food or any ingredient thereof, if the changed allergenic property results from such treatment or processing.

(Secs. 401, 403(j), 701(e), 52 Stat. 1046 as amended, 1048, 70 Stat. 919 (21 U.S.C. 341, 343(j), 371(e)).)

§ 105.65 Infant foods.

(a) If a food (other than a dietary supplement of vitamins and/or minerals alone) purports to be or is represented for special dietary use for infants, the label shall bear, if such food is fabricated from two or more ingredients, the common or usual name of each ingredient, including spices, flavoring, and coloring.

(b) If such food, or any ingredient thereof, consists in whole or in part of plant or animal matter and the name of such food or ingredient does not clearly reveal the specific plant or animal which is its source, such name shall be so qualified as to reveal clearly the specific plant or animal that is such source.

(c) If such use of the food is by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk, the label shall also bear:

(1) A statement of the percent by weight or weight per unit volume of moisture, protein, fat, available carbohydrate, ash, and crude fiber contained in such food.

(2) A statement of the number of available kilocalories (in the case of food label statements, a kilocalorie is represented by the word "Calorie") supplied by a specified quantity of such food as customarily or usually prepared for consumption.

(3) A statement of the amount of each vitamin or mineral listed in paragraph (c)(5) of this section and the amount of other added vitamin(s) and mineral(s) supplied by a specified quantity of such food as customarily or usually prepared for consumption.

(4) The statement "This product should not be used as the sole source of protein in the infant diet" if a quantity which supplies 100 available kilocalories of such food as customarily or usually prepared for consumption contains less than 1.8 grams of protein of a biological quality equivalent to that of casein, or if

the amount and biological quality of protein per 100 available kilocalories of such food are such that the quality of protein expressed as a fraction of that of casein multiplied by the amount of protein in grams is less than 1.8, or if the biological quality of protein is less than 70 percent of that of casein.

(i) For the purpose of this paragraph (c)(4), the method for determining biological quality of protein shall be the method prescribed on page 800 (secs. 39.166–39.170) under "Biological Evaluation of Protein Quality—Official, Final Action" of "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th edition (1970).[2]

(ii) For the purpose of this paragraph (c)(4), the method for determining the amount of protein is to multiply by 6.25 the total nitrogen content in grams, as determined by the method described on page 16 (sec. 2.051) under "Improved Kjeldahl Methods for Nitrate-Free Samples—Official, Final Action" of "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th edition (1970).[2]

(5) If a quantity which supplies 100 available kilocalories of such food as customarily or usually prepared for consumption contains less than the following amounts of vitamins and minerals, a statement that an additional quantity of such vitamin(s) or mineral(s), as the case may be, should be supplied from other sources:

Vitamins and minerals	Unit of measurement	Minimum amounts
Vitamin A	International units	250
Vitamin D	do	40
Vitamin E	do	0.3
Ascorbic acid (vitamin C)	Milligrams	7.8
Thiamine (vitamin B_1)	do	0.025
Riboflavin (vitamin B_2)	do	0.06
Niacin [1]	Milligram equivalents	0.8
Vitamin B_6	Milligrams	0.035
Folacin	Micrograms	4
Pantothenic acid	Milligrams	0.3
Vitamin B_{12}	Micrograms	0.15
Calcium	Milligrams	100
Phosphorus	do	25
Magnesium	do	6
Iron	do	1
Iodine	Micrograms	5
Copper	Milligrams	0.06

[1] The generic term "niacin" includes niacin (nicotinic acid), niacinamide (nicotinamide), and 1 mg equivalent for each 60 milligrams of tryptophan in the food.

When a statement prescribed by this paragraph (c)(5) is required, it shall appear in immediate proximity to the statement for the appropriate vitamin or mineral required by paragraph (c)(3) of this section. The difference in quantity between the amount of vitamin(s) and mineral(s) supplied and the amount required by this paragraph, expressed on the same basis, must also appear in the same statement.

(6) If such food contains fat at a level supplying less than 15 percent of the total available kilocalories, or linoleic acid (present as a glyceride) at a level supplying less than 2 percent of the total available kilocalories, a statement that an additional quantity of fat or linoleic acid (linoleate), as the case may be, should be supplied from other sources. The requirement of this paragraph (c)(6) shall not apply to such food which purports to be or is represented for special dietary use by reason of a need for regulating the intake of fat.

(d) The provisions of paragraph (c) of this section shall not apply to whole milk (of cows) or evaporated milk except with respect to ascorbic acid, vitamin D, and iron under paragraph (c)(5) of this section.

(e) A food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk, and which complies with the provisions of this section, shall be exempt from the effective provisions of §§ 105.67 and 105.77.

§ 105.67 Certain label statements relating to certain food used in control of body weight or in dietary management with respect to disease.

If a food purports to be or is represented for special dietary use by man by reason of its use as a means of regulating the intake of protein, fat, carbohydrate, or calories, for the purpose of controlling body weight, or for the purpose of dietary management with respect to disease, the label shall bear a statement of:

(a) The percent by weight of protein, fat, and available carbohydrates in such food; and

(b) The number of available calories supplied by a specified quantity of such food.

§ 105.69 Foods used to regulate sodium intake.

If a food purports to be or is represented for special dietary use by man by reason of its use as a means of regulating the intake of sodium or salt (sodium chloride), the label shall bear a statement of the number of milligrams of sodium in 100 grams of such food and a statement of the number of milligrams of sodium in a specified serving of such food. The number of milligrams of sodium shall be declared as the nearest multiple of 5 milligrams, as determined by appropriate analysis, except that, if such food contains not more than 10 milligrams of sodium in 100 grams of the food and not more than 10 milligrams of sodium in a specified serving of the food, the label shall bear a statement to that effect.

(Secs. 401, 403(j), 701(e), 52 Stat. 1046 as amended, 1048, 70 Stat. 919 (21 U.S.C. 341, 343(j), 371(e)).)

§ 105.77 Vitamins and minerals.

(a) *Vitamins and minerals for which U.S. RDA's are established.* If a food purports or is represented to be for special dietary use because of vitamin or mineral properties for which U.S. RDA's have been established, the label shall bear a statement of the percentage of the U.S. RDA of such vitamins and minerals, as set forth in § 105.3(b), supplied by such food when consumed in a specified quantity during a period of 1 day. The quantity specified shall be a reasonable quantity suitable for and practicable of consumption within 1 day. The order in which the nutrients appear on the label shall be the order in § 105.3(b), except when other regulations provide otherwise. Immediately preceding the declaration of vitamin and mineral content, the following heading shall be stated, "Percentage of U.S. Recommended Daily Allowances (U.S. RDA)." If such purported or represented special dietary use is for persons within more than one group for which U.S. RDA's are established, such statement shall include the percentage for each group. When the percentage of the U.S. RDA is a whole number and a fraction or a whole number and a decimal, it shall be expressed as the whole number disregarding the fraction or decimal. The total quantity of vitamins or minerals in a food shall be no less than the amount declared, and no more than a reasonable amount above the declared quantity. Reasonable variations caused by heat, light, oxidation, storage, transportation, or unavoidable deviations in good manufacturing practice are recognized.

(b) *Vitamins and minerals for which no U.S. RDA's are established.* If a food purports or is represented to be for special dietary use because of the presence of a vitamin or mineral for which no U.S. RDA has been established, the quantity of each such nutrient (in the order listed in § 105.3(c), except when other regulations provide otherwise) supplied by the food when consumed in a specified quantity during a period of 1 day shall be stated on the label in standard metric units of weight followed by the statement "No U.S. Recommended Daily Allowance (U.S. RDA) has been established for this nutrient" or by an asterisk referring to another asterisk at the bottom of the table and followed by that statement. The quantity of consumption specified shall be a reasonable quantity suitable for and practicable of consumption within 1 day.

(c) *Applicability.* When paragraphs (a) and (b) of this section are both applicable: information required by paragraph (b) with respect to vitamins shall follow immediately after information required by paragraph (a) with respect to vitamins; information required by paragraph (b) with respect to minerals shall follow immediately after information required by paragraph (a) with respect to minerals; and the quantity of consumption specified pursuant to each paragraph shall be the same.

(d) *Iodized salt.* The requirements of this section shall not apply to iodized salt when the declared content of the iodine compound in the salt is equivalent to 0.01 percent by weight iodine.

(Secs. 201(n), 401, 403 (a) and (j), 411, 701 (a) and (e), 52 Stat. 1041, 1046–1048, 1055, 70 Stat. 919, 90 Stat. 410–411 (21 U.S.C. 321 (n), 341, 343 (a) and (j), 350, 371 (a) and (e)).)

See footnote 2 on p. 14326.

§ 105.79 Nonnutritive constitutents.

If a food purports to be or is represented for special dietary use by man by reason of the presence of any constituent which is not utilized in normal metabolism, the label shall bear a statement of the percent by weight of such constituent, and, in juxtaposition with the name of such constituent, the word "nonnutritive". If such constituent is fibrous plant matter, it shall be considered to be crude fiber and its percent expressed as such. But if such constituent is saccharin or a saccharin salt, the label shall bear, in lieu of such statement and word, the statement "Contains ____ saccharin (or saccharin salt, as the case may be), a nonnutritive, artificial sweetener which should be used only by persons who must restrict their intake of ordinary sweets," the blank to be filled in with the percent by weight of saccharin or saccharin salt in such food. The provisions of this section shall not be construed as authorizing the use of saccharin or its salts in any food other than one for use by persons who must restrict their intake of carbohydrates, or as relieving any food from compliance with any requirement of sections 402 (b) or (d), 403(g), or other provisions of the act.

Subpart C—[Reserved]

Subpart D—Standards of Identity

§ 105.85 Dietary supplements of vitamins and minerals.

(a) *General provisions*—(1) *Articles subject to this regulation; "dietary supplements."* The dietary supplements of vitamins and/or minerals for which definitions and standards of identity are prescribed by this section are prepared and offered as tablets, capsules, wafers, or other similar uniform units; in powder, granular, flake, or liquid form; or in the physical form of conventional foods; and purport to be or are represented for special dietary use by man to supplement his diet by increasing the total dietary intake of one or more of the essential vitamins and/or minerals specified in paragraph (d) of this section. The dietary supplements of vitamins and/or minerals are henceforth referred to as "dietary supplements" in this section.

(2) *Articles not subject to this regulation.* This section does not apply to:

(i) Any food which contains or consists of any vitamin or mineral listed in § 105.3(b)(1), or any combination thereof, provided that all of the following requirements are met: (a) No such nutrient is contained at a level of 50 percent or more of the adult U.S. RDA per serving for that nutrient, (b) no direct or implied representation is made on the label, in labeling, or in advertising that the product is a dietary supplement or is adequate or appropriate for supplementing the daily diet with essential nutrients, and (c) the product is labeled pursuant to § 101.9 of this chapter.

(ii) Foods the composition of which is defined by other regulations, e.g., other foods for which definitions and standards of identity or nutritional quality guidelines have been promulgated, or statutes.

(iii) Any food represented for use as the sole item of a meal or of the diet.

(iv) Foods represented for use solely under medical supervision to meet nutritional requirements in specific medical conditions.

(v) Conventional foods to which one or more nutrient(s) listed in paragraph (d)(1) of this section are added to improve nutritional quality, unless the total level, including any naturally occurring amounts, of any such added vitamin or mineral per single serving attains or exceeds 50 percent of the U.S. Recommended Daily Allowance (U.S. RDA) for adults and children 4 years or more of age as specified in § 105.3(b)(1), in which case the provisions of both this section and § 101.9 of this chapter shall apply. If the provisions of both this section and § 101.9 of this chapter apply to a food, the labeling of such food shall conform to the labeling established in this section except that the labeling established in § 101.9(c) of this chapter, including the order for listing vitamins and minerals established in § 101.9(c)(7)(iv) of this chapter, shall be used in lieu of the labeling established in paragraph (i)(1) of this section.

(vi) Raw agricultural commodities.

(vii) A food with nutrients restored to pre-processing levels or added pursuant to § 101.3(e) of this chapter so that it is not nutritionally inferior to the food for which it substitutes and which it resembles.

(3) *Enforcement.* Any food product that meets the definition of a dietary supplement in paragraph (a)(1) of this section and which is not subject to any of the exemptions set forth in paragraph (a)(2) of this section and which fails to comply with the requirements of this section, including a multicomponent supplement not subject to paragraph (e) of this section which offers an added vitamin or mineral not permitted by this section or which offers a greater potency of any vitamin or mineral than is permitted by this section, will be deemed to be in violation of section 403(g) of the Federal Food, Drug, and Cosmetic Act (hereafter "the act"), which provides that a food shall be deemed to be misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed, unless it conforms to the definition and standard.

(4) *Other requirements of law.* Compliance with the requirements of this section does not exempt a dietary supplement from other requirements of any other applicable regulations, whether or not cross-referenced herein.

(5) *Amendments to this standard.* Amendment of the permissible combinations of vitamins and/or minerals, as established in paragraph (b) of this section, or of the permitted range of potency for any vitamin(s) or mineral(s) in a dietary supplement, as established in paragraph (c) of this section, or any other amendments to this section, may be proposed by the Commissioner of Food and Drugs on his own initiative or upon petition by an interested person in accordance with the procedure set forth in Part 2 of this chapter. Any such petition shall show that such amendment will promote honesty and fair dealing in the interest of consumers.

(b) *Inclusion of vitamins and minerals in dietary supplements.* Except as provided in paragraph (e) of this section: (1) A dietary supplement consisting of more than one vitamin or mineral shall contain only those vitamins and/or minerals listed in paragraph (d)(1) of this section and shall be offered for its vitamin and/or mineral content only in the following combinations, with the provision that any vitamin or mineral defined as optional in paragraph (d)(1) of this section may be omitted:

(i) All vitamins and minerals.

(ii) All vitamins.

(iii) All minerals.

(iv) All vitamins and the mineral iron.

(v) A dietary supplement of vitamins A, D, and C, represented for use by infants and/or children under 4 years of age, composed of vitamin A, vitamin D and vitamin C. Vitamin E and/or iron may be included as optional ingredients in such a preparation: *Provided,* That inclusion of the optional ingredients vitamin D and/or phosphorous in the dietary supplements identified in paragraph (b)(1)(i), (ii), (iii) or (iv) of this section does not require inclusion of any additional optional ingredients. Inclusion of the optional ingredients biotin and pantothenic acid and/or copper and zinc in such products does not require inclusion of vitamin D and/or phosphorus when the latter two nutrients are optional. Inclusion of any of the other optional ingredients (biotin or pantothenic acid for vitamins and copper or zinc for minerals) in such products requires the inclusion of both such optional ingredients if the product is a multivitamin or multimineral supplement, and requires the inclusion of all four such ingredients if the product is a multivitamin and multimineral supplement; and: *Provided further,* That folic acid is optional for liquid dietary supplements because of instability of the vitamin in liquid preparations. A liquid dietary supplement represented as a "multivitamin" preparation but not containing folic acid shall bear the following statement on the label: "This product does not contain the essential vitamin folic acid," which shall immediately follow the listing of vitamins and minerals as prescribed in paragraph (i) of this section.

(2) A dietary supplement may also be composed of a single vitamin or mineral.

(c) *Potency of vitamins and minerals in dietary supplements.* (1) Except as provided in paragraph (e) of this section, and subject to good manufacturing practices, dietary supplements shall contain in the specified daily quantity not less than the lower limit nor more than the upper limit of any nutrient specified in paragraph (d)(1) of this section for the groups for which the supplement is offered.

(2) For the purposes of this section, the term "daily quantity" means the

quantity of a dietary supplement that shall be specified in the labeling for consumption in a period of 1 day, and which shall be an amount or number of units reasonably suitable for and practicable of consumption in 1 day.

(d) *U.S. Recommended Daily Allowance.* (1) The following table sets forth the permissible qualitative and quantitative composition of dietary supplements of vitamins and/or minerals for purposes of paragraphs (b) and (c):

U.S. recommended daily allowances (U.S. RDA's) and permissible compositional ranges for dietary supplements of vitamins and minerals

	Unit of measurement	Children under 4 years of age [1]			Adults and children 4 or more years of age			Pregnant or lactating women		
		Lower limit	U.S. RDA	Upper limit	Lower limit	U.S. RDA	Upper limit	Lower limit	U.S. RDA	Upper limit
Vitamins—Mandatory:										
Vitamin A	International units	1,250	2,500	2,500	2,500	5,000	5,000	5,000	8,000	8,000
Vitamin D [2]	do	200	400	400				400	400	400
Vitamin E	do	5	10	15	15	30	45	30	30	60
Vitamin C	Milligrams	20	40	[illegible]	30	60	90	60	60	120
Folic acid [3]	do	.1	.2	.3	.2	.4	.4	.4	.8	.8
Thiamine	do	.35	.70	1.05	.75	1.50	2.25	1.50	1.70	3.00
Riboflavin	do	.4	.8	1.2	.8	1.7	2.6	1.7	2.0	3.4
Niacin	do	4.5	9.0	13.5	10.0	20.0	30.0	20.0	20.0	40.0
Vitamin B_6	do	.35	.70	1.05	1.00	2.00	3.00	2.00	2.50	4.00
Vitamin B_{12}	Micrograms	1.5	3.0	4.5	3.0	6.0	9.0	6.0	8.0	12.0
Optional:										
Vitamin D	International units				200	400	400			
Biotin	Milligrams	.075	.150	0.225	.150	.300	.450	.300	.300	.600
Pantothenic acid	do	2.5	5.0	7.5	5.0	10.0	15.0	10.0	10.0	20.0
Minerals—Mandatory:										
Calcium	Grams	.125	.800	1.200	.125	1.000	1.500	.125	1.300	2.000
Phosphorus [4]	do	.125	.800	1.200	.125	1.000	1.500			
Iodine	Micrograms	35	70	105	75	150	[illegible]	150	150	300
Iron	Milligrams	5	10	15	9	18	[illegible]	[illegible]	18	60
Magnesium	do	40	200	[illegible]	100	400	[illegible]	100	450	800
Optional:										
Phosphorus [4]	Grams							.125	1.300	2.000
Copper	Milligrams	.5	1.0	1.5	1.0	2.0	3.0	1.0	2.0	4.0
Zinc	do	4.0	8.0	12.0	7.5	15.0	22.5	7.5	15.0	30.0

[1] When labeled for use by infants, a dietary supplement shall contain not less than the lower limit designated for a nutrient in this set of columns, nor more than 100 percent of the infant U.S. RDA for a nutrient as prescribed in sec. 125.1(b) of this chapter except that the level of biotin, when used, shall be 0.05 mg daily recommended quantity.
[2] Optional for adults and children 4 or more years of age.
[3] Optional for liquid products.
[4] Optional for pregnant or lactating women. When present, the quantity of phosphorus may be not greater than the quantity of calcium.

(2) The U.S. Recommended Daily Allowances (U.S. RDA's) have been derived by the Food and Drug Administration from the "'Recommended Dietary Allowances," published by the Food and Nutrition Board, National Academy of Sciences/National Research Council, and are subject to amendment as more knowledge on human nutrient requirements becomes available.

(3) For determining the percentage of the U.S. RDA present in a dietary supplement, the quantitative content of the following vitamins shall be calculated in terms of the following chemically identifiable reference forms:

Reference form

Vitamin	Name	Empirical formula	Molecular weight
Vitamin C	*L*-Ascorbic acid	$C_6H_8O_6$	176.12
Folic acid	Pteroyl mono-*L*-glutamic acid	$C_{19}H_{19}N_7O_6$	441.41
Thiamine	Thiamine chloride hydrochloride	$C_{12}H_{17}ClN_4OS \cdot HCl$	337.28
Riboflavin	Riboflavin	$C_{17}H_{20}N_4O_6$	376.37
Niacin	Nicotinic acid	$C_6H_5NO_2$	123.11
Vitamin B_6	Pyridoxine	$C_8H_{11}NO_3$	169.18
Vitamin B_{12}	Cyanocobalamin	$C_{63}H_{88}CoN_{14}O_{14}P$	1,355.40
Biotin	*D*-Biotin	$C_{10}H_{16}N_2O_3S$	244.31
Pantothenic acid	*D*-Pantothenic acid	$C_9H_{17}NO_5$	219.23

(4) In addition to the nutrients listed in paragraph (d)(1) of this section, other vitamins and minerals recognized as essential or probably essential in human nutrition in their biologically active forms but for which no U.S. RDA's have been established are: vitamin K, choline, and the minerals chlorine, chromium, fluorine, manganese, molybdenum, nickel, potassium, selenium, silicon, sodium, tin, and vanadium.

(e) *Exemption from limitations on inclusion of ingredients and from maximum potency restrictions for certain dietary supplements.* (1) Pursuant to section 411 (a)(1) of the act, the limitations established by paragraphs (b) and (d) of this section and by § 105.60(b)(5) with respect to the inclusion of vitamins, minerals, and other ingredients in dietary supplements, and the maximum limits on potency established by paragraphs (c) and (d) of this section shall not apply to a food for special dietary use, defined in § 105.3(a)(1), which is or contains any vitamin or mineral and which complies with the following criteria:

(i) The preparation is intended for ingestion in tablet, capsule, or liquid form, or, if not intended for ingestion in such a form, does not simulate and is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet; and

(ii) The preparation is not represented for use by individuals in treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women.

(2) For purposes of paragraph (e)(1) of this section: a food shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure; and the term "children" means individuals who are under the age of 12 years.

(3) The exemption provided by section 411(a)(1) of the act and paragraph (e)(1) of this section does not apply to minimum potency requirements established by this section. Whenever a vitamin or mineral for which a U.S. RDA has been established is included in a dietary supplement, the supplement shall provide in the recommended daily quantity at least the lower potency limit for the vitamin or mineral established by the table in paragraph (d)(1) of this section.

(4) The exemption provided by section 411(a)(1) of the act and paragraph (e)(1) of this section does not apply to restrictions on maximum potency imposed by the act or by regulations for reasons of safety under paragraph (f) of this section.

(f) *Restrictions on maximum potency of vitamins and minerals for reasons of safety.* Restrictions of the maximum potency of a vitamin or mineral may be imposed for reasons of safety by the act or by regulation. For convenience, certain restrictions are cross-referenced below:

(1) Vitamin A—See § 250.109 of this chapter.

(2) Vitamin D—See § 250.110 of this chapter.

(3) Folic acid—See § 172.345 of this chapter.

(4) Iodine—See §§ 172.365 and 172.375 of this chapter.

(5) Copper—See § 182.5260 of this chapter.

(6) Fluorine—See § 170.45 of this chapter.

(7) Potassium—See § 201.306 of this chapter.

(8) Any vitamin or mineral which is included in a dietary supplement and which is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown to be safe under the conditions of its intended use is a food additive within the meaning of section 201(s) of the act; and pursuant to sections 402(a)(2)(C) and 409 of the act, such inclusion is illegal in the absence of a food additive regulation approving such inclusion. A listing of some of the vitamins, minerals, and compounds with vitamin and/or mineral properties which are generally recognized as safe, and which thus may lawfully be included in a dietary supplement without a food additive regulation, appears at Subpart F of Part 182 of this chapter.

(g) *Acceptable ingredient sources for dietary supplements:* (1) A vitamin or mineral used in a dietary supplement may be supplied by any suitable substance which is not a food additive as defined in section 201(s) of the act; or if it is a food additive as so defined, it shall be used in conformity with regulations established pursuant to section 409 of the act.

(2) Any safe and suitable substance may be used as preservative, stabilizer, flavor, sweetener, color, seasoning, carrier, base, or vehicle, or to facilitate preparation of vitamin or mineral substances. A dietary supplement shall be prepared so that any such substance contained therein does not exceed the amount reasonably required to accomplish its intended physical or technical effect, and so that the biological availability of the vitamin(s) and mineral(s) is not impaired by the presence of such substance. Any such substance shall not be a food additive or color additive as defined in section 201 (s) or (t) of the act; or if it is a food additive or color additive as so defined, it shall be used in conformity with regulations established pursuant to section 409 or 706 of the act.

(h) *Nomenclature.* (1) The name of a dietary supplement shall consist of a term descriptive of the vitamin and/or mineral composition of the product, as established in paragraph (h)(2) of this section, together with a phrase or phrases designating the group(s) for which the supplement is intended, as established in paragraph (h)(3) of this section, e.g., "multivitamin and multimineral supplement for children under 4 years of age"; "dietary supplement of vitamin C and E for adults". The name of the dietary supplement shall appear prominently and conspicuously on the principal display panel(s) of the label. The letters or phrase(s) designating the consumer group(s) for which the product is represented shall be no less than one-third the size of those used in the term descriptive of the composition of the product. In addition to the name prescribed by this paragraph, a dietary supplement may be labeled with a proprietary name: *Provided,* That it is not false or misleading in any particular.

(2) The terms used to describe the vitamin and/or mineral composition of dietary supplements shall be as follows:

(i) "Multivitamin and multimineral supplement" for a dietary supplement containing all vitamins and minerals identified as "mandatory," for the group(s) for which the supplement is offered, in the table in paragraph (d)(1) of this section.

(ii) "Multivitamin supplement" for a dietary supplement containing all vitamins identified as "mandatory," for the group(s) for which the supplement is offered, in the table in paragraph (d)(1) of this section.

(iii) "Multimineral supplement" for a dietary supplement containing all minerals identified as "mandatory," for the group(s) for which the supplement is offered, in the table in paragraph (d)(1) of this section.

(iv) "Multivitamin and iron supplement" or "multivitamin supplement with iron" for a dietary supplement containing all vitamins identified as "mandatory," for the group(s) for which the supplement is offered, in the table in paragraph (d)(1) of this section and the mineral iron.

(v) "_____ supplement" for a dietary supplement containing a single vitamin or mineral listed in paragraph (d) of this section (the blank to be filled in with the name of the vitamin or mineral).

(vi) "Dietary supplement of vitamins A, D, and C" for a preparation complying with paragraph (b)(1)(v) of this section, provided that if vitamin E is included, the term shall read "* * * vitamins A, D, C, and E * * *," and that if iron is included, the term shall conclude with "* * * with iron" or "* * * and iron."

(vii) If, pursuant to section 411(a)(1) of the act and paragraph (e)(1) of this section, the dietary supplement contains more than one vitamin or mineral but does not meet the criteria for any of the preparations identified in paragraph (h)(2)(i) through (vi) of this section, the preparation shall bear a term that is accurately descriptive of its vitamin and/or mineral composition, e.g., "dietary supplement of vitamins A, C, and E." The term "multivitamin" shall not be used to describe a product which fails to provide all of the vitamins identified as "mandatory," for the group(s) for which the supplement is offered, in the table in paragraph (d), except as provided in the second proviso clause of paragraph (b)(1) of this section with respect to a liquid multivitamin preparation which does not include folic acid, and the term "multivitamin" shall not be used to describe a product which fails to provide all of the minerals identified as "mandatory," for the group(s) for which the supplement is offered, in the table in paragraph (d)(1) of this section.

(3) The phrases used to designate the group(s) for which a dietary supplement is intended shall be as follows:

(i) "For infants."

(ii) "For children under 4 years of age."

(iii) "For adults and children 4 or more years of age."

(iv) "For pregnant or lactating women."

(v) If, pursuant to section 411(a)(1) of the act and paragraph (e)(1) of this section, a dietary supplement does not comply with the formulation and potency criteria established in paragraphs (b) and (c) of this section, the supplement may not be offered for any of the groups identified in paragraph (h)(3)(i) through (iv) because the exemption from formulation and potency restrictions authorized by section 411(a)(1) of the act and paragraph (e)(1) of this section does not apply to preparations offered for use by persons under 12 years of age or by pregnant or lactating women. Such a preparation shall accurately identify the group for which it is offered, e.g., "For adults" or "For persons 12 years of age or older, other than pregnant or lactating women."

(i) *Format for listing vitamins and minerals.* (1) Immediately following the name of the dietary supplement (i.e., the term descriptive of the vitamin and/or mineral composition of the product together with the phrase or phrases designating the group(s) for which the supplement is intended, as required by paragraph (h) of this section) on the principal display panel, or on the information panel pursuant to § 101.2 of this chapter if insufficient space is available on the principal display panel, the label shall bear a listing in tabular form of each of the vitamins and/or minerals supplied by the specified daily quantity of the dietary supplement, such daily quantity being specified at the top of the list. (In the event a dietary supplement is offered for more than one group, the specified daily quantity and listing of vitamins and/or minerals for each group shall be stated separately on the label.) The vitamins and/or minerals shall be described by the names appearing in paragraph (d) of this section and shall be grouped and identified separately as "vitamins" and/or "minerals" without reference to "mandatory" or "optional." Within each category (i.e., "vitamins" and "minerals"), the vitamins or minerals shall appear in the order listed in paragraph (d) of this section. The quantity of each vitamin and/or mineral present in a specified daily quantity of the dietary supplement shall be stated as a part of this list and expressed in percentage of the U.S. RDA for each group for which the supplement is offered. The quantity of each vitamin and/or mineral present in the specified daily quantity of the dietary supplement shall also appear in the tabular listing in terms of the unit of measure specified in paragraph (d)(1) of this section: *Provided,* That if the dietary supplement includes a vitamin or mineral for which no U.S. RDA has been established, the listing shall state the quantity in standard metric units of weight of each such nutrient supplied by the food when consumed in the specified quantity during a period of 1 day, ac-

companied by the statement "No U.S. Recommended Daily Allowance (U.S. RDA) has been established for this nutrient," or followed by an asterisk referring to another asterisk placed at the bottom of the table and followed by that statement.

(2) For determining the percentage contents of the U.S. RDA's present in the dietary supplement, the quantitative content of the following vitamins shall be calculated in terms of the following chemically identifiable reference forms:

Reference form

Vitamin	Name	Empirical formula	Molecular weight
Vitamin C	*L*-Ascorbic acid	$C_6H_8O_6$	176.12
Folic acid	Pteroyl mono-*L*-glutamic acid	$C_{19}H_{19}N_7O_6$	441.41
Thiamine	Thiamine chloride hydrochloride	$C_{12}H_{17}ClN_4OS \cdot HCl$	337.28
Riboflavin	Riboflavin	$C_{17}H_{20}N_4O_6$	376.37
Niacin	Nicotinic acid	$C_6H_5NO_2$	123.11
Vitamin B_6	Pyridoxine	$C_8H_{11}NO_3$	169.18
Vitamin B_{12}	Cyanocobalamin	$C_{63}H_{88}CoN_{14}O_{14}P$	1,355.40
Biotin	*D*-Biotin	$C_{10}H_{16}N_2O_3S$	244.31
Pantothenic acid	*D*-Pantothenic acid	$C_9H_{17}NO_5$	219.23

(3) The following synonyms may be added in parentheses immediately following the name of the vitamin in the listing described in paragraph (i)(1) of this section:

Vitamin	*Synonym*
Vitamin C	Ascorbic acid.
Folic acid	Folacin.
Riboflavin	Vitamin B_2.
Thiamine	Vitamin B_1.

(j) *List of ingredients.* A separate list of all ingredients used in the manufacture of the product shall be included on the panel pursuant to the requirements of Part 101 of this chapter. Such list shall include the natural source or chemical form of each individual nutrient present in the dietary supplement.

(k) *Dietary supplements containing alcohol.* When a dietary supplement is in liquid form and contains alcohol, the label shall state the percent-by-volume of alcohol present.

(l) *Expiration date.* A dietary supplement containing one or more nutrients subject to deterioration below the labeled value before consumption shall bear on its outside wrapper or container, as well as on the label of its immediate container, the statement: "Expiration date ---------," the blank to be filled in with a month and year. The expiration date shall be the date selected by the manufacturer, packer, or distributor of the dietary supplement on the basis of tests or other information showing that the dietary supplement, until that date, under the conditions of handling, storage, and use prescribed by directions appearing on its label, or, in the absence of such prescribed directions, under customary or usual conditions of handling, storage and use, will contain not less than the quantity of each such vitamin and/or mineral, as set forth on its label, when consumed.

(m) *Conspicuousness of labeling.* All labeling information required by this section shall appear with the conspicuousness required by section 403(f) of the act and §101.2 of this chapter. In addition, the following labeling requirements shall be met:

(1) The list of nutrients required by paragraph (i)(1) of this section shall appear in uniform type size.

(2) The synonyms permitted by paragraph (i)(3) of this section, if used, and the list of ingredients required by paragraph (j) of this section shall appear in uniform type size, and in type size no larger than that used for the list of nutrients required by paragraph (i)(1) of this section.

(n) *Certain labeling prohibitions.* Because dietary supplements are foods for special dietary use, the labels and labeling for dietary supplements are subject to the prohibitions contained in § 105.60(b) in addition to the requirements of this section.

(Secs. 201(n), 401, 403 (a) and (j), 411, 701 (a) and (e), 52 Stat. 1041, 1046–1048, 1055, 70 Stat. 919, 90 Stat. 410–411 (21 U.S.C. 321 (n), 341, 343 (a) and (j), 350, 371 (a) and (e)).)

PART 108—EMERGENCY PERMIT CONTROL

Subpart A—General Provisions

Sec.

108.3 Definitions.
108.5 Determination of the need for a permit.
108.6 Revocation of determination of need for permit.
108.7 Issuance or denial of permit.
108.10 Suspension and reinstatement of permit.
108.12 Manufacturing, processing, or packing without a permit, or in violation of a permit.
108.19 Establishment of requirements for exemption from section 404 of the act.

Subpart B—Specific Requirements and Conditions for Exemption From or Compliance With an Emergency Permit

108.35 Thermal processing of low-acid foods packaged in hermetically sealed containers.

AUTHORITY: Secs. 402, 404, 701, 52 Stat. 1046–1047 as amended, 1048, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 342, 344, 371).

Subpart A—General Provisions

§ 108.3 Definitions.

(a) The definitions contained in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part.

(b) "Commissioner" means the Commissioner of Food and Drugs.

(c) "Act" means the Federal Food, Drug, and Cosmetic Act, as amended.

(d) "Permit" means an emergency permit issued by the Commissioner pursuant to section 404 of the act for such temporary period of time as may be necessary to protect the public health.

(e) "Manufacture, processing, or packing of food in any locality" means activities conducted in a single plant or establishment, a series of plants under a single management, or all plants in an industry or region, by a manufacturer, processor, or packer.

§ 108.5 Determination of the need for a permit.

(a) Whenever the Commissioner determines after investigation that a manufacturer, processor, or packer of a food for which a regulation has been promulgated in Subpart B of this part does not meet the mandatory conditions and requirements established in such regulation, he shall issue to such manufacturer, processor, or packer an order determining that a permit shall be required before the food may be introduced or delivered for introduction into interstate commerce by that person. The order shall specify the mandatory conditions and requirements with which there is a lack of compliance.

(1) The manufacturer, processor, or packer shall have 3 working days after receipt of such order within which to file objections. Such objections may be filed by telegram, telex, or any other mode of written communication addressed to the Food and Drug Administration, Bureau of Foods, 200 C St. SW., Washington, DC 20204. If such objections are filed, the determination is stayed pending a hearing to be held within 5 working days after the filing of objections on the issues involved unless the Commissioner determines that the objections raise no genuine and substantial issue of fact to justify a hearing.

(2) If the Commissioner finds that there is an imminent hazard to health, the order shall contain this finding and the reasons therefor, and shall state that the determination of the need for a permit is effective immediately pending an expedited hearing.

(b) A hearing under this section shall be conducted by the Commissioner or his designee at a location agreed upon by the objector and the Commissioner or, if such agreement cannot be reached, at a location designated by the Commissioner. The manufacturer, processor, or packer shall have the right to cross-examine the Food and Drug Administration's witnesses and to present witnesses on his own behalf.

(c) Within 5 working days after the hearing, and based on the evidence presented at the hearing, the Commissioner shall determine whether a permit is required and shall so inform the manufacturer, processor, or packer in writing, with the reasons for his decision.

(d) The Commissioner's determination of the need for a permit constitutes final agency action from which appeal lies to the courts. The Commissioner will not stay a determination of the need for a permit pending court appeal except in unusual circumstances, but will participate in expediting any such appeal.

§ 108.6 Revocation of determination of need for permit.

(a) A permit shall be required only during such temporary period as is necessary to protect the public health.

(b) Whenever the Commissioner has reason to believe that a permit holder is in compliance with the mandatory requirements and conditions established in Subpart B of this part and is likely to remain in compliance, he shall, on his own initiative or on the application of the permit holder, revoke both the determination of need for a permit and the permit that had been issued. If denied, the applicant shall, upon request, be afforded a hearing conducted in accordance with § 108.5 (b) and (c) as soon as practicable. Such revocation is without prejudice to the initiation of further permit proceedings with respect to the same manufacturer, processor, or packer should later information again show the need for a permit.

§ 108.7 Issuance or denial of permit.

(a) After a determination and notification by the Commissioner in accordance with the provisions of § 108.5 that a manufacturer, processor, or packer requires a permit, such manufacturer, processor, or packer may not thereafter introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by him unless he holds a permit issued by the Commissioner or obtains advance written approval of the Food and Drug Administration pursuant to § 108.12(a).

(b) Any manufacturer, processor, or packer for whom the Commissioner has made a determination that a permit is necessary may apply to the Commissioner for the issuance of such a permit. The application shall contain such data and information as is necessary to show that all mandatory requirements and conditions for the manufacturer, processing or packing of a food for which regulations are established in Subpart B of this part are met and, in particular, shall show that the deviations specified in the Commissioner's determination of the need for a permit have been corrected or suitable interim measures established. Within 10 working days after receipt of such application, (except that the Commissioner may extend such time an additional 10 working days where necessary), the Commissioner shall issue a permit, deny the permit, or offer the applicant a hearing conducted in accordance with § 108.5 (b) and (c) as to whether the permit should be issued. The Commissioner shall issue such a permit to which shall be attached, in addition to the mandatory requirements and conditions of Subpart B of this part, any additional requirements or conditions which may be necessary to protect the public health if he finds that all mandatory requirements and conditions of Subpart B of this part are met or suitable interim measures are established.

(c) Denial of a permit constitutes final agency action from which appeal lies to the courts. The Commissioner will not stay such denial pending court appeal except in unusual circumstances, but will participate in expediting any such appeal.

§ 108.10 Suspension and reinstatement of permit.

(a) Whenever the Commissioner finds that a permit holder is not in compliance with the mandatory requirements and conditions established by the permit, he shall immediately suspend the permit and so inform the permit holder, with the reasons for the suspension.

(b) Upon application for reinstatement of a permit, the Commissioner shall, within 10 working days, reinstate the permit if he finds that the person is in compliance with the mandatory requirements and conditions established by the permit or deny the application.

(c) Any person whose permit has been suspended or whose application for reinstatement has been denied may request a hearing. The hearing shall be conducted by the Commissioner or his designee within 5 working days of receipt of the request at a location agreed upon by the objector and the Commissioner or, if an agreement cannot be reached, at a location designated by the Commissioner. The permit holder shall have the right to present witnesses on his own behalf and to cross-examine the Food and Drug Administration's witnesses.

(d) Within 5 working days after the hearing, and based on the evidence presented at the hearing, the Commissioner shall determine whether the permit shall be reinstated and shall so inform the permit holder, with the reasons for his decision.

(e) Denial of an application for reinstatement of a permit constitutes final agency action from which appeal lies to the courts. The Commissioner will not stay such denial pending court appeal except in unusual circumstances, but will participate in expediting any such appeal.

§ 108.12 Manufacturing, processing, or packing without a permit, or in violation of a permit.

(a) A manufacturer, processor, or packer may continue at his own risk to manufacture, process, or pack without a permit a food for which the Commissioner has determined that a permit is required. All food so manufactured, processed, or packed during such period without a permit shall be retained by the manufacturer, processor, or packer and may not be introduced or delivered for introduction into interstate commerce without the advance written approval of the Food and Drug Administration. Such approval may be granted only upon an adequate showing that such food is free from microorganisms of public health significance. The manufacturer, processor, or packer may provide to the Commissioner, for his consideration in making any such determination, an evaluation of the potential public health significance of such food by a competent authority in accordance with procedures recognized as being adequate to detect any potential hazard to public health. Within 20 working days after receipt of a written request for such written approval the Food and Drug Administration shall either issue such written approval or deny the request. If the request is denied, the applicant shall, upon request, be afforded a prompt hearing conducted in accordance with § 108.5 (b) and (c).

(b) Except as provided in paragraph (a) of this section, no manufacturer, processor, or packer may introduce or deliver for introduction into interstate commerce without a permit or in violation of a permit a food for which the Commissioner has determined that a permit is required. Where a manufacturer, processor, or packer utilizes a consolidation warehouse or other storage facility under his control, interstate shipment of any such food from the point of production to that warehouse or storage facility shall not violate this paragraph, provided that no further introduction or delivery for introduction into interstate commerce is made from that consolidated warehouse or storage facility except as provided in paragraph (a) of this section.

§ 108.19 Establishment of requirements for exemption from section 404 of the act.

(a) Whenever the Commissioner finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with microorganisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he shall promulgate regulations in Subpart B of this part establishing requirements and conditions governing the manufacture, processing, or packing of the food necessary to protect the public health. Such regulations may be proposed by the Commissioner on his own initiative or in response to a petition from any interested person pursuant to Part 2 of this chapter.

(b) A manufacturer, processor, or packer of a food for which a regulation has been promulgated in Subpart B of this part shall be exempt from the requirement for a permit only if he meets all of the mandatory requirements and conditions established in that regulation.

Subpart B—Specific Requirements and Conditions for Exemption From or Compliance With an Emergency Permit

§ 108.35 Thermal processing of low-acid foods packaged in hermetically sealed containers.

(a) Inadequate or improper manufacture, processing, or packing of thermally processed low-acid foods in hermetically sealed containers may result in the distribution in interstate commerce of processed foods that may be injurious to health. The harmful nature of such foods cannot be adequately determined after these foods have entered into interstate commerce. The Commissioner of Food and Drugs therefore finds that, in order to protect the public health, it may

be necessary to require any commercial processor, in any establishment engaged in the manufacture, processing, or packing of thermally processed low-acid foods in hermetically sealed containers, to obtain and hold a temporary emergency permit provided for under section 404 of the Federal Food, Drug, and Cosmetic Act. Such a permit may be required whenever the Commissioner finds, after investigation, that the commercial processor has failed to fulfill all the requirements of this section, including registration and the filing of process information, and the mandatory portions of Part 113 of this chapter. These requirements are intended to ensure safe manufacture, processing, and packing procedures and to permit the Food and Drug Administration to verify that these procedures are being followed. Such failure shall constitute prima facie basis for the immediate application of the emergency permit control provisions of section 404 of the act to that establishment, pursuant to the procedures established in Subpart A of this part.

(b) The definitions in § 113.3 of this chapter are applicable when such terms are used in this section.

(c) Registration and process filing. (1) *Registration.* A commercial processor when first engaging in the manufacture, processing, or packing of thermally processed low-acid foods in hermetically sealed containers in any state, as defined in section 201(a)(1) of the act, shall, not later than 10 days after first so engaging, register with the Food and Drug Administration on Form FD–2541 (food canning establishment registration) information including (but not limited to) his name, principal place of business, the location of each establishment in which such processing is carried on, the processing method in terms of the type of processing equipment employed, and a list of the low-acid foods so processed in each such establishment. These forms are available from the Food and Drug Administration, Bureau of Foods, Industry Guidance Branch, HFF–326, 200 C St. SW., Washington, DC 20204, or at any Food and Drug Administration district office. The completed form shall be submitted to the Food and Drug Administration, Bureau of Foods, Division of Food Technology, HFF–419, 200 C St. SW., Washington, DC 20204. Commercial processors presently so engaged shall register not later than July 13, 1973. Commercial processors duly registered in accordance with this section shall notify the Food and Drug Administration not later than 90 days after such commercial processor ceases or discontinues the manufacture, processing, or packing of thermally processed foods in any establishment: *Provided,* That such notification shall not be required as to the temporary cessation necessitated by the seasonal character of the particular establishment's production or caused by temporary conditions including but not limited to strikes, lockouts, fire, or acts of God.

(2) *Process filing.* A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers shall, not later than 60 days after registration and prior to the packing of a new product, provide the Food and Drug Administration information as to the scheduled processes including but not limited to the processing method, type of retort or other thermal processing equipment employed, minimum initial temperatures, times and temperatures of processing, sterilizing value (F_0), or other equivalent scientific evidence of process adequacy, critical control factors affecting heat penetration, and source and date of the establishment of the process, for each such low-acid food in each container size: *Provided,* That the filing of such information does not constitute approval of the information by the Food and Drug Administration, and that information concerning processes and other data so filed shall be regarded as trade secrets within the meaning of 21 U.S.C. 331(j) and 18 U.S.C. 1905. This information shall be submitted on the following forms as appropriate: Form FD–2541a (food canning establishment and process filing for still retort processes), Form FD–2541b (food canning establishment and process filing for agitating processes), or Form FD–2541c (food canning establishment and process filing for other than still retort and agitating processes). These forms are available from the Food and Drug Administration, Bureau of Foods, Industry Guidance Branch, HFF–326, 200 C St. SW., Washington, DC 20204, or at any Food and Drug Administration district office. The completed form(s) shall be submitted to the Food and Drug Administration, Bureau of Foods, Division of Food Technology, HFF–419, 200 C St. SW., Washington, DC 20204.

(i) If all the necessary information is not available for existing products, the processor shall, at the time the existing information is provided to the Food and Drug Administration request in writing an extension of time for submission of such information, specifying what additional information is to be supplied and the date by which it is to be submitted. Within 30 working days after receipt of such request the Food and Drug Administration shall either grant or deny such request in writing.

(ii) If a packer intentionally makes a change in a previously filed scheduled process by reducing the initial temperature or retort temperature, reducing the time of processing, or changing the product formulation, the container, or any other condition basic to the adequacy of scheduled process, he shall prior to using such changed process obtain substantiation by qualified scientific authority as to its adequacy. Such substantiation may be obtained by telephone, telegram, or other media, but must be promptly recorded, verified in writing by the authority, and contained in the packer's files for review by the Food and Drug Administration. Within 30 days after first use, the packer shall submit to the Food and Drug Administration, Bureau of Foods, 200 C St. SW., HFF–419, Washington, DC 20204 a complete description of the modifications made and utilized, together with a copy of his file record showing prior substantiation by a qualified scientific authority as to the safety of the changed process. Any intentional change of a previously filed scheduled process or modification thereof in which the change consists solely of a higher initial temperature, a higher retort temperature, or a longer processing time, shall not be considered a change subject to this paragraph, but if that modification is thereafter to be regularly scheduled, the modified process shall be promptly filed as a scheduled process, accompanied by full information on the specified forms as provided in this paragraph.

(iii) Many packers employ an "operating" process in which retort operators are instructed to use retort temperatures and/or processing times slightly in excess of those specified in the scheduled process as a safety factor to compensate for minor fluctuations in temperature or time to assure that the minimum times and temperatures in the scheduled process are always met. This would not constitute a modification of the scheduled process.

(3) *Process adherence and information.* (i) A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers in any registered establishment shall process each low-acid food in each container size in conformity with at least the scheduled processes and modifications filed pursuant to paragraph (c)(2) of this section.

(ii) Process information availability: When requested by the Food and Drug Administration in writing, a commercial processor engaged in thermal processing of low-acid foods packaged in hermetically sealed containers shall provide the Food and Drug Administration with any information concerning processes and procedures which is deemed necessary by the Food and Drug Administration to determine the adequacy of the process: *Provided,* That the furnishing of such information does not constitute approval of the information by the Food and Drug Administration, and that the information concerning processes and other data so furnished shall be regarded as trade secrets within the meaning of 21 U.S.C. 331(j) and 18 U.S.C. 1905.

(d) A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers shall promptly report to the Food and Drug Administration any instance of spoilage or process deviation the nature of which indicates potential health significance where any lot of such food has in whole or in part entered distribution.

(e) A commercial processor engaged in thermal processing of low-acid foods packaged in hermetically sealed containers shall promptly report to the Food and Drug Administration any instance wherein any lot of such food, which may be injurious to health by reason of contamination with microorganisms, has in whole or in part entered distribution.

(f) A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers shall have prepared and in his files a current procedure which he will use for products under his control and which he will ask his distributor to follow, including plans for effecting recalls of any product that may be injurious to health; for identifying, collecting, warehousing, and controlling the product; for determining the effectiveness of such recall; for notifying the Food and Drug Administration of any such recall; and for implementing such recall program.

(g) All operators of retorts, thermal processing systems, aseptic processing and packaging systems, or other thermal processing systems, and container closure inspectors shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction in retort operations, aseptic processing and packaging systems operations or other thermal processing systems operations, and container closure inspections, and has satisfactorily completed the prescribed course of instruction: *Provided*, That this requirement shall not apply in the State of California as listed in paragraph (j) of this section and shall not apply until March 25, 1975 in any other State. The Commissioner will not withhold approval of any school qualified to give such instruction.

(h) A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers shall prepare, review, and retain at the processing plant for a period of not less than one year, and at the processing plant or other reasonably accessible location for an additional two years, all records of processing, deviations in processing, container closure inspections, and other records specified in Part 113 of this chapter. If during the first year of the three-year record retention period the processing plant is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack. Upon written demand during the course of a factory inspection pursuant to section 704 of the act by a duly authorized employee of the Food and Drug Administration, a commercial processor shall permit the inspection and copying by such employee of these records to verify the adequacy of processing, the integrity of container closures, and the coding of the products.

(i) This section shall not apply to the commercial processing of any food processed under the continuous inspection of the meat and poultry inspection program of the Animal and Plant Health Inspection Service of the Department of Agriculture under the Federal Meat Inspection Act (34 Stat. 1256, as amended by 81 Stat. 584 (21 U.S.C. 601 et seq.)) and the Poultry Products Inspection Act (71 Stat. 441, as amended by 82 Stat. 791 (21 U.S.C. 451 et seq.)).

(j) Compliance with State regulations: (1) Wherever the Commissioner finds that any State regulates the commercial thermal processing of low-acid foods in accordance with effective regulations specifying at least the requirements of Part 113 of this chapter, he shall issue a notice stating that compliance with such State regulations shall constitute compliance with Part 113 of this chapter. However, the provisions of this section shall remain applicable to the commercial processing of low-acid foods in any such State, except that, either the State through its regulatory agency or each processor of low-acid foods in such State shall filed with the Bureau of Foods the registration information and the processing information prescribed in paragraph (c) of this section.

(2) The Commissioner finds that the regulations adopted by the State of California under the laws relating to cannery inspections governing thermal processing of low-acid foods packaged in hermetically sealed containers satisfy the requirements of Part 113 of this chapter.

Accordingly, processors, who under the laws relating to cannery inspections are licensed by the State of California and who comply with such state regulations, shall be deemed to comply with the requirements of Part 113 of this chapter.

(k) Imports: (1) This section shall apply to any foreign commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers and offering such foods for import into the United States except that, in lieu of providing for the issuance of an emergency permit under paragraph (a) of this section, the Commissioner will request the Secretary of the Treasury to refuse admission into the United States, pursuant to section 801 of the act, of any such low-acid foods which the Commissioner determines, after investigation, may result in the distribution in interstate commerce of processed foods that may be injurious to health as set forth in paragraph (a) of this section.

(2) Any such food refused admission shall not be admitted until such time as the Commissioner may determine that the commercial processor offering the food for import is in compliance with the requirements and conditions of this section and that such food is not injurious to health. For the purpose of making such determination, the Commissioner reserves the right for a duly authorized employee of the Food and Drug Administration to inspect the commercial processor's manufacturing, processing, and packing facilities.

(l) The following data and information submitted to the Food and Drug Administration pursuant to this section are not available for public disclosure unless they have been previously disclosed to the public as defined in § 4.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 4.61 of this chapter:

(1) Manufacturing methods or processes, including quality control information.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for publice disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

PART 109—UNAVOIDABLE CONTAMINANTS IN FOOD AND FOOD-PACKAGING MATERIAL

Subpart A—General Provisions

Sec.

109.3 Definitions and interpretations.
109.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

Subpart B—Tolerances for Unavoidable Poisonous or Deleterious Substances

109.30 Temporary tolerances for polychlorinated biphenyls (PCB's).

AUTHORITY: Secs. 402(a), 406, 409, 701, 52 Stat. 1046 as amended, 1049 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948, 72 Stat. 1785–1788 as amended (21 U.S.C. 342(a), 346, 348, 371).

Subpart A—General Provisions

§ 109.3 Definitions and interpretations.

(a) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable to such terms when used in this part.

(b) Unavoidable natural, environmental, or industrial contaminants include any poisonous or deleterious substance added to any food where such substance cannot be avoided by good manufacturing practice.

§ 109.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

(a) Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and nonflammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment, causing the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn caused the contamination of food products intended for human

consumption (meat, milk and eggs). Investigations by the Food and Drug Administration have revealed that a significant percentage of paper food-packaging material contains PCB's which can migrate to the packaged food. The origin of PCB's in such material is not fully understood. Reclaimed fibers containing carbonless copy paper (contains 3 to 5 percent PCB's) have been identified as a primary source of PCB's in paper products. Some virgin paper products have also been found to contain PCB's, the source of which is generally attributed to direct contamination from industrial accidents from the use of PCB-containing equipment and machinery in food packaging manufacturing establishments. Since PCB's are toxic chemicals, the PCB contamination of food-packaging materials as a result of industrial accidents, which can cause the PCB contamination of food, represents a hazard to public health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in establishments manufacturing food-packaging materials.

(b) The following special provisions are necessary to preclude the accidental PCB contamination of food-packaging materials:

(1) New equipment or machinery for manufacturing food-packaging materials shall not contain or use PCB's.

(2) On or before September 4, 1973, the management of establishments manufacturing food-packaging materials shall:

(i) Have the heat exchange fluid used in existing equipment for manufacturing food-packaging materials sampled and tested to determine whether it contains PCB's or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must to the fullest extent posible commensurate with current good manufacturing practices be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the establishment any other PCB-containing equipment, machinery and materials wherever there is a reasonable expectation that such articles could cause food-packaging materials to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iii) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be given to (*a*) its toxicity; (*b*) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (*c*) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (*d*) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently non-hazardous is to be made on an individual installation and operation basis.

(c) The provisions of this section do not apply to electrical transformers and condensers containing PCB's in sealed containers.

Subpart B—Tolerances for Unavoidable Poisonous or Deleterious Substances

§ 109.30 Temporary tolerances for polychlorinated biphenyls (PCB's).

(a) Polychlorinated biphenyls (PCB's) are toxic, industrial chemicals. Because of their widespread, uncontrolled industrial applications, PCB's have become a persistent and ubiquitous contaminant in the environment. As a result, certain foods and animal feeds, principally those of animal and marine origin, contain PCB's as unavoidable, environmental contaminants. PCB's are transmitted to the food portion (meat, milk, and eggs) of food-producing animals ingesting PCB-contaminated animal feed. In addition, a significant percentage of paper food-packaging materials contain PCB's which may migrate to the packaged food. The source of PCB's in paper food-packaging materials is primarily of certain types of carbonless copy paper (containing 3 to 5 percent PCB's) in waste paper stocks used for manufacturing recycled paper. Therefore, temporary tolerances for residues of PCB's as unavoidable environmental or industrial contaminants are established for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph, the term "polychlorinated biphenyls (PCB's)" is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB's is present as the residue. The temporary tolerances for residues of PCB's are as follows:

(1) 2.5 parts per million in milk (fat basis).

(2) 2.5 parts per million in manufactured dairy products (fat basis).

(3) 5 parts per million in poultry (fat basis).

(4) 0.5 parts per million in eggs.

(5) 0.2 parts per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes).

(6) 2 parts per million in animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food producing animals.

(7) 5 parts per million in fish and shellfish (edible portion). The edible portion of fish excludes head, scales, viscera, and inedible bones.

(8) 0.2 parts per million in infant and junior foods.

(9) 10 parts per million in paper food-packaging material intended for or used with human food, finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled "Analytical Methodology for Polychlorinated Biphenyls, February 1973" for determining compliance with the tolerances established in this section is available from the Hearing Clerk, Department of Health, Education, and Welfare, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857.

NOTE: At 38 FR 22794, Aug. 24, 1973, the following appeared concerning § 109.30(a)(9) (formerly 122.10)(a)(9):

• • • § 109.30(a)(9) is hereby stayed pending full review of the objections and requests for hearing. • • •

In the interim, as stated in the final order (38 FR 18098) the Food and Drug Administration will enforce the temporary tolerance level established by § 109.30(a)(9) by seizing any paper food-packaging material shipped in interstate commerce after September 4, 1973 containing higher than the specified level of PCB's as adulterated in violation of sec. 402 of the act.

PART 110—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING HUMAN FOOD

Subpart A—General Provisions

Sec.
110.1 Current good manufacturing practice.
110.3 Definitions.
110.10 Personnel.
110.19 Exclusions.

Subpart B—Buildings and Facilities

110.20 Plants and grounds.
110.35 Sanitary facilities and controls.
110.37 Sanitary operations.

Subpart C—Equipment

110.40 Equipment and procedures.

Subpart D—[Reserved]

Subpart E—Production and Process Controls

110.80 Processes and controls.
110.99 Natural or unavoidable defects in food for human use that present no health hazard.

AUTHORITY: Secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a)(4), 371(a)) unless otherwise noted.

Subpart A—General Provisions

§ 110.1 Current good manufacturing practice.

The criteria in §§ 110.10, 110.19, 110.20, 110.35, 110.37, 110.40, 110.80, and 110.99 shall apply in determining whether the facilities, methods, practices, and controls used in the manufacture, processing, packing, or holding of food are in conformance with or are operated or administered in conformity with good manufacturing practices to assure that food for human consumption is safe and has been prepared, packed, and held under sanitary conditions.

§ 110.3 Definitions.

The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this

part. The following definitions shall also apply:

(a) "Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(b) "Plant" means the building or buildings or parts thereof, used for or in connection with the manufacturing, processing, packaging, labeling, or holding of human food.

(c) "Sanitize" means adequate treatment of surfaces by a process that is effective in destroying vegetative cells of pathogenic bacteria and in substantially reducing other microorganisms. Such treatment shall not adversely affect the product and shall be safe for the consumer.

§ 110.10 Personnel.

The plant management shall take all reasonable measures and precautions to assure the following:

(a) *Disease control.* No person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds, or other abnormal sources of microbiological contamination, shall work in a food plant in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated by such person, or of disease being transmitted by such person to other individuals.

(b) *Cleanliness.* All persons, while working in direct contact with food preparation, food ingredients, or surfaces coming into contact therewith shall:

(1) Wear clean outer garments, maintain a high degree of personal cleanliness, and conform to hygienic practices while on duty, to the extent necessary to prevent contamination of food products.

(2) Wash their hands thoroughly (and sanitize if necessary to prevent contamination by undesirable microorganism) in an adequate hand-washing facility before starting work, after each absence from the work station and at any other time when the hands may have become soiled or contaminated.

(3) Remove all insecure jewelry and, during periods where food is manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized.

(4) If gloves are used in food handling, maintain them in an intact, clean, and sanitary condition. Such gloves should be of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

(5) Wear hair nets, headbands, caps, or other effective hair restraints.

(6) Not store clothing or other personal belongings, eat food or drink beverages, or use tobacco in any form in areas where food or food ingredients are exposed or in areas used for washing equipment or utensils.

(7) Take any other necessary precautions to prevent contamination of foods with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicants.

(c) *Education and training.* Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food-handling techniques and food-protection principles and should be cognizant of the danger of poor personal hygiene and insanitary practices.

(d) *Supervision.* Responsibility for assuring compliance by all personnel with all requirements of this Part 110 shall be clearly assigned to competent supervisory personnel.

§ 110.19 Exclusions.

The following operations are excluded from coverage under these general regulations, however, the Commissioner will issue special regulations when he believes it necessary to cover these excluded operations: Establishments engaged solely in the harvesting, storage, or distribution of one or more raw agricultural commodities, as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated or otherwise processed before being marketed to the consuming public.

Subpart B—Buildings and Facilities

§ 110.20 Plants and grounds.

(a) *Grounds.* The grounds about a food plant under the control of the operator shall be free from conditions which may result in the contamination of food including, but not limited to, the following:

(1) Improperly stored equipment, litter, waste, refuse, and uncut weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for rodents, insects, and other pests.

(2) Excessively dusty roads, yards, or parking lots that may constitute a source of contamination in areas where food is exposed.

(3) Inadequately drained areas that may contribute contamination to food products through seepage or foot-borne filth and by providing a breeding place for insects or microorganisms.

If the plant grounds are bordered by grounds not under the operator's control of the kind described in paragraph (a) (1) through (3) of this section, care must be exercised in the plant by inspection, extermination, or other means to effect exclusion of pests, dirt, and other filth that may be a source of food contamination.

(b) *Plant construction and design.* Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-processing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for sanitary operations and production of safe food. Floors, walls, and ceilings in the plant shall be of such construction as to be adequately cleanable and shall be kept clean and in good repair. Fixtures, ducts, and pipes shall not be so suspended over working areas that drip or condensate may contaminate foods, raw materials, or food-contact surfaces. Aisles or working spaces between equipment and between equipment and walls shall be unobstructed and of sufficient width to permit employees to perform their duties without contamination of food or food-contact surfaces with clothing or personal contact.

(2) Provide separation by partition, location, or other effective means for those operations which may cause contamination of food products with undesirable microorganisms, chemicals, filth, or other extraneous material.

(3) Provide adequate lighting to hand-washing areas, dressing and locker rooms, and toilet rooms and to all areas where food or food ingredients are examined, processed, or stored and where equipment and utensils are cleaned. Light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation shall be of the safety type or otherwise protected to prevent food contamination in case of breakage.

(4) Provide adequate ventilation or control equipment to minimize odors and noxious fumes or vapors (including steam) in areas where they may contaminate food. Such ventilation or control equipment shall not create conditions that may contribute to food contamination by airborne contaminants.

(5) Provide, where necessary, effective screening or other protection against birds, animals, and vermin (including, but not limited to, insects and rodents).

§ 110.35 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accomodations including, but not limited to, the following:

(a) *Water supply.* The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts foods or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature and under pressure as needed shall be provided in all areas where the processing of food, the cleaning of equipment, utensils, or containers, or employee sanitary facilities require.

(b) *Sewage disposal.* Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(c) *Plumbing.* Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Not constitute a source of contamination to foods, food products or ingredients, water supplies, equipment, or utensils or create an insanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal

operations release or discharge water or other liquid waste on the floor.

(d) *Toilet facilities.* Each plant shall provide its employees with adequate toilet and associated hand-washing facilities within the plant. Toilet rooms shall be furnished with toilet tissue. The facilities shall be maintained in a sanitary condition and kept in good repair at all times. Doors to toilet rooms shall be self-closing and shall not open directly into areas where food is exposed to airborne contamination, except where alternate means have been taken to prevent such contamination (such as double doors, positive air-flow systems, etc.). Signs shall be posted directing employees to wash their hands with cleaning soap or detergents after using toilet.

(e) *Hand-washing facilities.* Adequate and convenient facilities for hand washing and, where appropriate, hand sanitizing shall be provided at each location in the plant where good sanitary practices require employees to wash or sanitize and dry their hands. Such facilities shall be furnished with running water at a suitable temperature for hand washing, effective hand-cleaning and sanitizing preparations, sanitary towel service or suitable drying devices, and, where appropriate, easily cleanable waste receptacles.

(f) *Rubbish and offal disposal.* Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, prevent waste from becoming an attractant and harborage or breeding place for vermin, and prevent contamination of food, food-contact surfaces, ground surfaces, and water supplies.

§ 110.37 Sanitary operations.

(a) *General maintenance.* Buildings, fixtures, and other physical facilities of the plant shall be kept in good repair and shall be maintained in a sanitary condition. Cleaning operations shall be conducted in such a manner as to minimize the danger of contamination of food and food-contact surfaces. Detergents, sanitizers, and other supplies employed in cleaning and sanitizing procedures shall be free of significant microbiological contamination and shall be safe and effective for their intended uses. Only such toxic materials as are required to maintain sanitary conditions, for use in laboratory testing procedures, for plant and equipment maintenance and operation, or in manufacturing or processing operations shall be used or stored in the plant. These materials shall be identified and used only in such manner and under conditions as will be safe for their intended uses.

(b) *Animal and vermin control.* No animals or birds, other than those essential as raw material, shall be allowed in any area of a food plant. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of foods in or on the premises by animals, birds, and vermin (including, but not limited to, rodents and insects). The use of insecticides or rodenticides is permitted only under such precautions and restrictions as will prevent the contamination of food or packaging materials with illegal residues.

(c) *Sanitation of equipment and utensils.* All utensils and product-contact surfaces of equipment shall be cleaned as frequently as necessary to prevent contamination of food and food products. Nonproduct-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to minimize accumulation of dust, dirt, food particles, and other debris. Single-service articles (such as utensils intended for one-time use, paper cups, paper towels, etc.) should be stored in appropriate containers and handled, dispensed, used, and disposed of in a manner that prevents contamination of food or food-contact surfaces. Where necessary to prevent the introduction of undesirable microbiological organisms into food products, all utensils and product-contact surfaces of equipment used in the plant shall be cleaned and sanitized prior to such use and following any interruption during which such utensils and contact surfaces may have become contaminated. Where such equipment and utensils are used in a continuous production operation, the contact surfaces of such equipment and utensils shall be cleaned and sanitized on a predetermined schedule using adequate methods for cleaning and sanitizing. Sanitizing agents shall be effective and safe under conditions of use. Any facility, procedure, machine, or device may be acceptable for cleaning and sanitizing equipment and utensils if it is established that such facility, procedure, machine, or device will routinely render equipment and utensils clean and provide adequate sanitizing treatment.

(d) *Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment and utensils with product-contact surfaces should be stored in such a location and manner that product-contact surfaces are protected from splash, dust, and other contamination.

Subpart C—Equipment

§ 110.40 Equipment and procedures.

(a) *General.* All plant equipment and utensils should be (1) suitable for their intended use, (2) so designed and of such material and workmanship as to be adequately cleanable, and (3) properly maintained. The design, construction, and use of such equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces.

(b) *Use of polychlorinated biphenyls in food plants.* Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Arocior (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and nonflammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment and causing the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn cause the contamination of food intended for human consumption (meat, milk, and eggs). Since PCB's are toxic chemicals, the PCB contamination of food as a result of these accidents represents a hazard to human health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in the production, handling, and storage of food. The following special provisions are necessary to preclude accidental PCB contamination of food:

(1) New equipment, utensils, and machinery for handling or processing food in or around a food plant shall not contain PCB's.

(2) On or before September 4, 1973, the management of food plants shall:

(i) Have the heat exchange fluid used in existing equipment or machinery for handling or processing food sampled and tested to determine whether it contains PCB's, or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate from the food plant any PCB-containing food-contact surfaces of equipment or utensils and any PCB-containing lubricants for equipment or machinery that is used for handling or processing food.

(iii) Eliminate from the food plant any other PCB-containing materials wherever there is a reasonable expectation that such materials could cause food to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iv) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be given to (*a*) its toxicity; (*b*) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (*c*) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (*d*) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently nonhazardous is to be made on an individual installation and operation basis.

(3) For the purposes of this section, the provisions do not apply to electrical transformers and condensers containing PCB's in sealed containers.

Subpart D—[Reserved]

Subpart E—Production and Process Controls

§ 110.80 Processes and controls.

All operations in the receiving, inspecting, transporting, packaging, segregating, preparing, processing, and storing of food shall be conducted in accord with adequate sanitation principles. Overall sanitation of the plant shall be under the supervision of an individual assigned responsibility for this function. All reasonable precautions, including the following, shall be taken to assure that production procedures do not contribute contamination such as filth, harmful chemicals, undesirable microorganisms, or any other objectionable material to the processed product:

(a) Raw material and ingredients shall be inspected and segregated as necessary to assure that they are clean, wholesome, and fit for processing into human food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as required to remove soil or other contamination. Water used for washing, rinsing, or conveying of food products shall be of adequate quality, and water shall not be reused for washing, rinsing, or conveying products in a manner that may result in contamination of food products.

(b) Containers and carriers of raw ingredients should be inspected on receipt to assure that their condition has not contributed to the contamination or deterioration of the products.

(c) When ice is used in contact with food products, it shall be made from potable water and shall be used only if it has been manufactured in accordance with adequate standards and stored, transported, and handled in a sanitary manner.

(d) Food-processing areas and equipment used for processing human food should not be used to process nonhuman food-grade animal feed or inedible products unless there is no reasonable possibility for the contamination of the human food.

(e) Processing equipment shall be maintained in a sanitary condition through frequent cleaning including sanitization where indicated. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(f) All food processing, including packaging and storage, should be conducted under such conditions and controls as are necessary to minimize the potential for undesirable bacterial or other microbiological growth, toxin formation, or deterioration or contamination of the processed product or ingredients. This may require careful monitoring of such physical factors as time, temperature, humidity, pressure, flow-rate and such processing operations as freezing, dehydration, heat processing, and refrigeration to assure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of the processed products.

(g) Chemical, microbiological, or extraneous-material testing procedures shall be utilized where necessary to identify sanitation failures or food contamination, and all foods and ingredients that have become contaminated shall be rejected or treated or processed to eliminate the contamination where this may be properly accomplished.

(h) Packaging processes and materials shall not transmit contaminants or objectionable substances to the products, shall conform to any applicable food additive regulation (Parts 170 through 189 of this chapter), and should provide adequate protection from contamination.

(i) Meaningful coding of products sold or otherwise distributed from a manufacturing, processing, packing, or repacking activity should be utilized to enable positive lot identification to facilitate, where necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use. Records should be retained for a period of time that exceeds the shelf life of the product, except that they need not be retained more than 2 years.

(j) Storage and transportation of finished products should be under such conditions as will prevent contamination, including development of pathogenic or toxigenic microorganisms, and will protect against undesirable deterioration of the product and the container.

§ 110.99 Natural or unavoidable defects in food for human use that present no health hazard.

(a) Some foods, even when produced under current good manufacturing and/or processing practices, contain natural or unavoidable defects at lower levels that are not hazardous to health. The Food and Drug Administration establishes maximum levels for such defects in foods produced under good manufacturing and/or processing practices and uses these levels for recommending regulatory actions.

(b) Defect action levels are established for products whenever it is necessary and feasible. Such levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse failure to observe either the requirement in section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this part that food manufacturers must observe current good manufacturing practices. Evidence obtained through factory inspection indicating such a violation renders the food unlawful, even though the amounts of natural or unavoidable defects are lower than the currently established action levels. The manufacturer of food must at all times utilize quality control procedures which will reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food unlawful regardless of the defect level of the final food.

(e) Current action levels for natural and unavoidable defects in food for human use that present no health hazard are as follows. (Levels that have been adopted on a temporary basis prior to publication as a regulation may be obtained upon request at the Office of the Assistant Commissioner for Public Affairs, Food and Drug Administration, Room 15B-42, 5600 Fishers Lane, Rockville, MD 20857.)

PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS

Subpart A—General Provisions

Sec.
113.1 Current good manufacturing practice.
113.3 Definitions.
113.10 Personnel.

Subpart B—[Reserved]

Subpart C—Equipment

113.40 Equipment and procedures.

Subpart D—Control of Components, Food Product Containers, Closures, and In-Process Materials

113.60 Containers.

Subpart E—Production and Process Controls

113.81 Product preparation.
113.83 Establishing scheduled processes.
113.87 Operations in the thermal processing room.
113.89 Deviations in processing.

Subpart F—Records and Reports

113.100 Records.

AUTHORITY: Sec. 402(a)(4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a)(4), 371(a)).

Subpart A—General Provisions

§ 113.1 Current good manufacturing practice.

The criteria in §§ 113.10, 113.40, 113.60, 113.81, 113.83, 113.87, 113.89, and 113.100 shall apply in determining whether the facilities, methods, practices, and controls used by the commercial processor in the manufacture, processing, or packing of low-acid foods in hermetically sealed containers are operated or administered in a manner adequate to protect the public health.

§ 113.3 Definitions.

For the purposes of this part, the following definitions apply:

(a) "Aseptic processing and packaging" means the filling of a commercially sterilized cooled product into presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms.

(b) "Bleeders" means openings used to remove air, that enters with steam, from retorts and steam chambers and to promote circulation of steam in such re-

torts and steam chambers. Bleeders may serve as a means of removing condensate.

(c) "Coming-up-time" means the time which elapses between the introduction of steam into the closed retort and the time when the retort reaches the required processing temperature.

(d) "Commercial processor" shall include any person engaged in commercial, custom, and so-called sportsman processing or institutional (church, school, penal, or other organization) processing of food.

(e) "Commercial sterility" of food means the condition achieved by application of heat which renders such food free of viable forms of microorganisms having public health significance, as well as any microorganisms of nonhealth significance capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution. "Commercial sterility" of equipment and containers used for aseptic processing and packaging of food means the condition achieved by application of heat, chemical sterilant(s), or other appropriate treatment which renders such equipment and containers free of viable forms of microorganisms having public health significance as well as any microorganisms of nonhealth significance capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

(f) "Flame sterilizer" means an apparatus in which hermetically sealed containers are agitated at atmospheric pressure, by either continuous, discontinuous, or reciprocating movement, over gas flames to achieve sterilization temperatures. A holding period in a heated section may follow the initial heating period.

(g) "Headspace, gross" is the vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (the top of the double seam of a can or the top edge of a glass jar).

(h) "Headspace, net" of a container having a double seam, such as a can, is the vertical distance between the level of the product (generally the liquid surface) in the upright rigid container and the inside surface of the lid.

(i) "Hermetically sealed container" means a container which is designed and intended to be secure against the entry of microorganisms and to maintain the commercial sterility of its contents after processing.

(j) "Incubation" means the holding of a sample(s) at a specified temperature for a specified period of time before examination.

(k) "Initial temperature" means the average temperature of the contents of the coldest container to be processed at the time the sterilizing cycle begins, as determined after thorough stirring or shaking of the filled and sealed container.

(l) "Lot" means the product produced during a period of time indicated by a specific code.

(m) "Low-acid foods" means any foods, other than alcoholic beverages, with a finished equilibrium pH value greater than 4.6 and a water activity greater than 0.85 and also includes any normally low-acid fruits, vegetables, or vegetable products in which for the purpose of thermal processing the pH value is reduced by acidification. Tomatoes, pears, and pineapples, or the juices thereof, having a pH of less than 4.7 and figs having a pH of 4.9 or below shall not be classed as low-acid foods.

(n) "Minimum thermal process" means the application of heat to food, either before or after sealing in a hermetically sealed container, for a period of time and at a temperature scientifically determined to be adequate to ensure destruction of microorganisms of public health significance.

(o) "Retort" means any closed vessel or other equipment used for the thermal processing of foods.

(p) "Scheduled process" means the process selected by the processor as adequate under the conditions of manufacture for a given product to achieve commercial sterility. This process may be in excess of that necessary to ensure destruction of microorganisms of public health significance.

(q) "Shall" and "should." As used in this part, "shall" refers to mandatory requirements and "should" refers to recommended or advisory procedures or equipment.

(r) "Vents" means openings controlled by gate, plug cock, or other adequate valves used for the elimination of air during the venting period.

(s) "Water activity" or "a_w" means the vapor pressure of the food product divided by the vapor pressure of pure water under identical conditions of pressure and temperature.

§ 113.10 Personnel.

All operators of retorts, processing systems, and aseptic processing and packaging systems, and container closure inspectors shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction in retort operations, processing systems operations, aseptic processing and packaging systems operations, and container closure inspections, and has been identified by that school as having satisfactorily completed the prescribed course of instruction.

Subpart B—[Reserved]

Subpart C—Equipment

§ 113.40 Equipment and procedures.

(a) *Equipment and procedures for pressure processing in steam in still retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer with a temperature range of not more than 100° F in the processing range on a scale at least 7 inches in length. The scale divisions shall be no more than 2° F. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to ensure their accuracy. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch diameter opening, and shall be equipped with a one-sixteenth inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeder for external wells shall emit steam continuously during the entire processing period. Thermometers shall be installed where they can be accurately and easily read. A thermometer that has a divided mercury column or that deviates more than 1° F from the standard shall be repaired or replaced. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device.* There shall be an accurate temperature recording device for each still retort adjusted to agree within 1° F of the known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The chart graduations shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 50° F per inch within a range of 20° F of the processing temperature. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature recorder bulb well shall have a one-sixteenth inch or larger bleeder opening emitting steam continuously during the processing period.

(3) *Pressure gages.* Each retort shall be equipped with a pressure gage. The gage should be graduated in divisions of 2 pounds or less, should be connected to the retort shell or external well by a short gooseneck tube, and should be not more than 4 inches higher than the gooseneck. The gage should be checked for accuracy at least once a year.

(4) *Steam controller.* Each retort shall be equipped with a steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Steam inlet.* The steam inlet to each still retort shall be large enough to provide sufficient steam for proper operation of the retort. Steam may enter either the top portion or the bottom portion of the retort but, in any case, shall enter the portion of the retort opposite the vent; for example, steam inlet in bottom portion and vent in top portion.

(6) *Crate supports.* A bottom crate support shall be employed in vertical still retorts. Baffle plates shall not be used in the bottom of still retorts.

(7) *Steam spreaders.* Steam spreaders, which are perforated or other style continuations of the steam line inside the retort, should not be larger than the

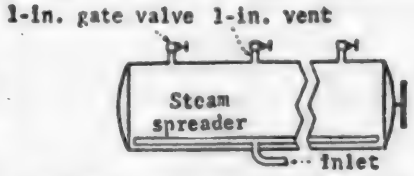
steam inlet line. Horizontal still retorts shall be equipped with steam spreaders that extend along the bottom for the length of the retort; the perforations should be along the top 90° of this pipe. Horizontal still retorts over 30 feet long should have two steam inlets connected to the spreader. In vertical still retorts the steam spreaders, if used, should be in the form of a cross with the perforations along the top or sides of the pipe. The number of perforations in spreaders for both horizontal and vertical still retorts should be such that the total cross-sectional area of the perforations is equal to 1½ to 2 times the cross-sectional area of the steam inlet line.

(8) *Bleeders.* Bleeders, except those for thermometer wells, shall be one-eighth inch or larger and shall be wide open during the entire process, including the coming-up-time. For horizontal retorts, bleeders shall be located within approximately 1 foot of each end; additional bleeders shall be located not more than 8 feet apart along the top. Vertical retorts shall have at least one bleeder opening located in that portion of the retort opposite the steam inlet. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to ensure removal of condensate. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(9) *Stacking equipment and position of containers.* Crates, trays, gondolas, etc., for holding containers shall be made of strap iron, adequately perforated sheet metal, or other suitable material. When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1-inch holes on 2-inch centers. If dividers are used between the layers of containers, they should be perforated as above. When there is stratification of the product in the containers, the containers should be processed in such a position that the plane of stratification is vertical.

(10) *Vents.* Vents shall be installed in such a way that air is removed from the retort before timing of the process is started. Vents shall be controlled by gate, plug cock, or other adequate type valves which shall be fully open to permit rapid discharge of air from the retort during the venting period. Vents shall not be connected directly to a closed drain system. If the overflow is used as a vent, there shall be an atmospheric break in the line before it connects to a closed drain. The vent shall be located in that portion of the retort opposite the steam inlet; for example, steam inlet in bottom portion and vent in top portion. Where a retort manifold connects several vent pipes from a single still retort, it shall be controlled by a gate, plug cock, or other adequate type valve. The retort manifold shall be of a size such that the cross-sectional area of the pipe is larger than the total cross-sectional area of all connecting vents. The discharge shall not be directly connected to a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifolds from several still retorts shall lead to the atmosphere. The manifold header shall not be controlled by a valve and shall be of a size such that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from all retorts venting simultaneously. Timing of the process shall not begin until the retort has been properly vented and the processing temperature has been reached. Retorts using air for pressure cooling shall be equipped with a ball or globe valve or suitable valve and piping arrangement on the air line to prevent air leakage into the retort during processing. Some typical installations and operating procedures reflecting the requirements of this section for venting still retorts are given in paragraphs (a) (10) (i) (*a*) through (*d*) and (ii) (*a*) and (*b*) of this section. Other installations and operating procedures which deviate from the above specifications may be used, provided that there is evidence that they accomplish adequate venting of air.

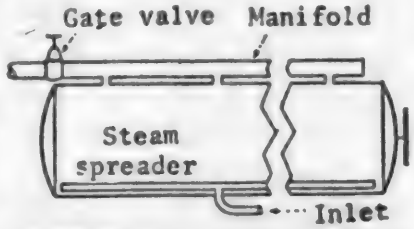
(i) *Venting horizontal retorts.* (*a*) Venting through multiple 1-inch vents discharging directly to atmosphere.



Specifications. One 1-inch vent for every 5 feet of retort length, equipped with a gate or plug cock valve and discharging to atmosphere; end vents not more than 2½ feet from ends of retort.

Venting method. Vent valves should be wide open for at least 5 minutes and to at least 225° F, or at least 7 minutes and to at least 220° F.

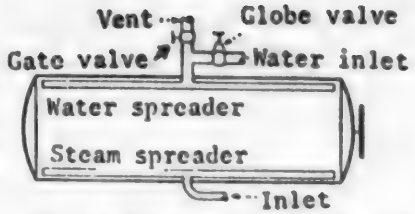
(*b*) Venting through multiple 1-inch vents discharging through a manifold to atmosphere.



Specifications. One 1-inch vent for every 5 feet of retort length; end vents not over 2½ feet from ends of retort; size of manifold—for retorts less than 15 feet in length, 2½ inches; for retorts 15 feet and over in length, 3 inches.

Venting method. Manifold vent gate or plug cock valve should be wide open for at least 6 minutes and to at least 225° F, or for at least 8 minutes and to at least 220° F.

(*c*) Venting through water spreaders.

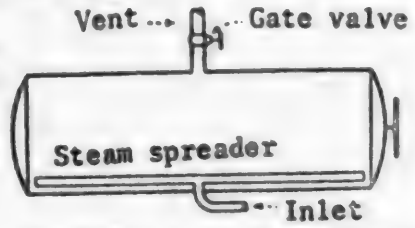


Size of water inlet, vent pipe, and vent valve. For retorts less than 15 feet in length, 2 inches; for retorts 15 feet and over in length, 2½ inches.

Size of water spreader. For retorts less than 15 feet in length, 1½ inches; for retorts 15 feet and over in length, 2 inches.

Venting method. Water spreader vent gate or plug cock valve should be wide open for at least 5 minutes and to at least 225° F, or for at least 7 minutes and to at least 220° F.

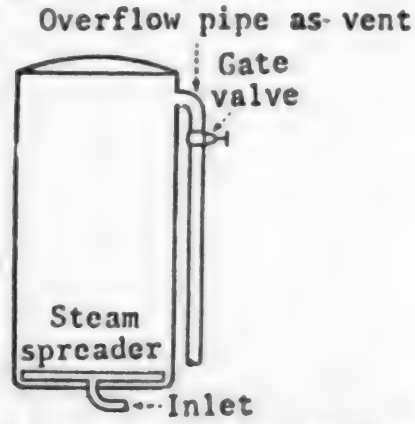
(*d*) Venting through a single 2½-inch top vent (for retorts not exceeding 15 feet in length).



Specifications: A 2½-inch vent equipped with a 2½-inch gate or plug cock valve and located within 2 feet of the center of the retort.

Venting method: Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 220° F.

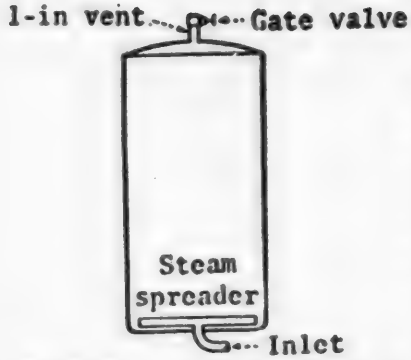
(ii) *Venting vertical retorts.* (*a*) Venting through a 1½-inch overflow.



Specifications. A 1½-inch overflow pipe equipped with a 1½-inch gate or plug cock valve and with not more than 6 feet of 1½-inch pipe beyond the valve before break to the atmosphere or to a manifold header.

Venting method. Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 218° F, or for at least 5 minutes and to at least 215° F.

(*b*) Venting through a single 1-inch side or top vent.



Specifications. A 1-inch vent in lid or top side, equipped with a 1-inch gate or plug cock valve and discharging directly into the atmosphere or to a manifold header.

Venting method. Vent gate or plug cock valve should be wide open for at least 5 minutes and to at least 230° F, or for at least 7 minutes and to at least 220° F.

(11) *Critical factors.* (i) Where maximum drained weight is specified in the scheduled process it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum (in vacuum-packed products) shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(b) *Equipment and procedures for pressure processing in water in still retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer that has a temperature range of not more than 100° F in the processing range on a scale at least 7 inches in length or a temperature range of not more than 150° F on a scale at least 9 inches in length. The scale divisions shall be no more than 2° F. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to ensure their accuracy. Bulbs of indicating thermometers shall be located in such a position that they are beneath the surface of the water throughout the process. On horizontal retorts this entry should be made in the side at the center, and the thermometer bulbs shall be inserted directly into the retort shell. In both vertical and horizontal retorts, the thermometer bulbs shall extend directly into the water a minimum of at least 2 inches without a separable well or sleeve. Thermometers shall be installed where they can be accurately and easily read. A thermometer that has a divided mercury column or that deviates more than 1° F from the standard shall be repaired or replaced. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device.* There shall be an accurate temperature recording device for each still retort adjusted to agree within 1° F of the known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The chart graduations shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 50° F per inch within a range of 20° F of the processing temperature. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The recording thermometer bulb should be located adjacent to the bulb of the mercury-in-glass thermometer except in the case of a vertical retort equipped with a combination recorder-controller. In such vertical retorts the temperature recorder-control bulb shall be located at the bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly. In horizontal retorts the temperature recorder-control bulb shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct steam impingement upon the control bulb.

(3) *Pressure gages.* (i) Each retort shall be equipped with a pressure gage. The gage should be graduated in divisions of 2 lbs. or less, should be connected to the retort shell or external well by a short gooseneck tube, and should be not more than 4 inches higher than the gooseneck. The gage should be checked for accuracy at least once a year.

(ii) An adjustable pressure relief, or control valve of a capacity sufficient to prevent undesired increase in retort pressure when the water valve is wide open and should be installed in the overflow line.

(4) *Steam introduction.* The distribution of steam in the bottom of the retort shall be accomplished in a manner adequate to provide uniform heat distribution throughout the retort. In vertical retorts, uniform steam distribution can be achieved by any of several methods. In horizontal retorts, the steam distributor shall run the length of the bottom of the retort with perforations distributed uniformly along the upper part of the pipe.

(5) *Crate supports.* A bottom crate support shall be employed in vertical still retorts. Baffle plates shall not be used in the bottom of the retort. Centering guides should be installed so as to ensure that there be about 1½-inches clearance between the side wall of the crate and the retort wall.

(6) *Stacking equipment.* Crates, trays, gondolas, etc., for holding containers shall be made of strap iron, adequately perforated sheet metal, or other suitable material. When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1-inch holes on 2-inch centers. If divider plates are used between the layers of containers, they should be perforated as above.

(7) *Drain valve.* A nonclogging, watertight valve shall be used. Screens should be installed over all drain openings.

(8) *Water level indicator.* There shall be a means of determining the water level in the retort during operation (e.g., by using a gage water glass or petcock(s)). Water shall cover the top layer of containers during the entire coming-up-time and processing periods and should cover the top layer of containers during the cooling periods.

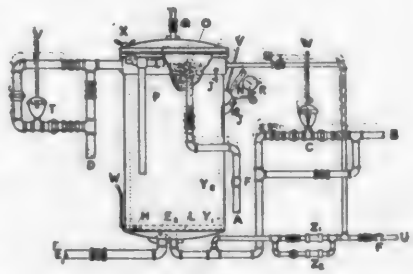
(9) *Air supply and controls.* In both horizontal and vertical still retorts for pressure processing in water, a means shall be provided for introducing compressed air at the proper pressure and rate. The proper pressure shall be controlled by an automatic pressure control unit. A check valve shall be provided in the air supply line to prevent water from entering the system. Air or water circulation shall be maintained continuously during the coming-up-time, processing, and cooling periods; if air is used to promote circulation it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort.

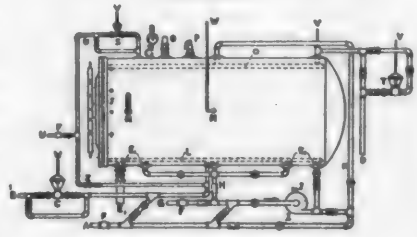
(10) *Cooling water supply.* In vertical retorts the cooling water should be introduced at the top of the retort between the water and container levels; in horizontal retorts the cooling water should be introduced into the suction side of the pump. A check valve should be included in the cooling water line.

(11) *Retort headspace.* The headspace necessary to control the air pressure should be maintained between the water level and the top of the retort shell.

(12) *Vertical and horizontal still retorts.* Vertical and horizontal still retorts should follow the arrangements in the following diagrams or be equivalent.

Vertical Retorts





LEGEND FOR VERTICAL AND HORIZONTAL STILL RETORTS

A—Water line.
B—Steam line.
C—Temperature control.
D—Overflow line.
E_1—Drain line.
E_2—Screens.
F—Check valves.
G—Line from hot water storage.
H—Suction line and manifold.
I—Circulating pump.
J—Petcocks.
K—Recirculating line.
L—Steam distributor.
M—Temperature controller bulb.
N—Thermometer.
O—Water spreader.
P—Safety valve.
Q—Vent valve for steam processing.
R—Pressure gage.
S—Inlet air control.
T—Pressure control.
U—Air line.
V—To pressure control instrument.
W—To temperature control instrument.
X—Wing nuts.
Y_1—Crate support.
Y_2—Crate guides.
Z—Constant flow orifice valve.
Z_1—Constant flow orifice valve used during come-up.
Z_2—Constant flow orifice valve used during cook.

(13) *Water circulation.* When a water circulating system is used for heat distribution it shall be installed in such a manner that water will be drawn from the bottom of the retort through a suction manifold and discharged through a spreader which extends the length of the top of the retort. The holes in the water spreader shall be uniformly distributed and should have an aggregate area not greater than the cross section area of the outlet line from the pump. The suction outlets should be protected with nonclogging screens to keep debris from entering the circulating system. The pump shall be equipped with a pilot light or other signaling device to warn the operator when it is not running, and with a bleeder to remove air when starting operations.

(14) *Critical factors.* (i) Where maximum drained weight is specified in the scheduled process it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum (in vacuum-packed products) shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(c) *Equipment and procedures for pressure processing in steam in continuous agitating retorts.*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer that has a temperature range of not more than 100° F in the processing range on a scale at least 7 inches in length. The scale divisions shall be no more than 2° F. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to ensure their accuracy. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch diameter opening, and shall be equipped with a ⅛-inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeders for external wells shall emit steam continuously during the entire processing period. Thermometers shall be installed where they can be accurately and easily read. A thermometer that has a divided mercury column or that deviates more than 1° F from the standard shall be repaired or replaced. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device.* There shall be an accurate temperature recording device for each retort adjusted to agree within 1° F of the known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The chart graduations shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 50° F per inch within a range of 20° F of the processing temperature. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature recorder bulb well shall have a ⅛-inch or larger bleeder opening emitting steam continuously during the processing period.

(3) *Pressure gages.* Each retort shall be equipped with a pressure gage. The gage should be graduated in divisions of 2 pounds or less, should be connected to the retort shell or external well by a short gooseneck tube, and should be not more than 4 inches higher than the gooseneck. The gage should be checked for accuracy at least once a year.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Bleeders.* Bleeders, except those for thermometer wells, shall be ⅛-inch or larger and shall be wide open during the entire process, including the coming-up time. Bleeders shall be located within approximately 1 foot of each end; additional bleeders shall be located not more than 8 feet apart along the top of the retort. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(6) *Venting and condensate removal.* Vents shall be located in that portion of the retort opposite the steam inlet. Air shall be removed before processing is started. At the time steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort and provision shall be made for continuing drainage of condensate during the retort operation. The condensate bleeder in the bottom of the shell serves as an indicator of continuous condensate removal.

(7) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The speed shall be adjusted and recorded when the retort is started, at any time a speed change is made, and at intervals of sufficient frequency to ensure that the retort speed is maintained as specified in the scheduled process. These adjustments and recordings should be made every 4 hours or less. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided.

(8) *Emergency stops.* If a retort jams or breaks down during processing operations, necessitating cooling the retort for repairs, the retort shall either be operated as a still retort, with all containers being given a full still retort process before the retort is cooled, or the retort shall be cooled promptly and all containers shall be either reprocessed, repacked and reprocessed, or discarded.

(i) Any containers in the retort intake valve of a continuous retort at the time of breakdown shall either be reprocessed, repacked and reprocessed, or discarded.

(ii) Both the time at which the reel stopped and the time the retort was used for a still retort process, if so used, shall be marked on the recording chart and entered on the other production records required in this chapter. If the alternative procedure of prompt cooling is followed, the subsequent handling methods used for the containers in the retort at the time of stopping and cooling shall be entered on the production records.

(9) *Temperature drop.* If the temperature of the continuous retort drops below the temperature specified in the scheduled process while containers are in the retort, the retort reel shall be stopped promptly. An automatic device should be used to stop the reel when the temperature drops below the specified process temperature. Before the reel is restarted, all containers in the retort shall be given a complete still retort process if the temperature drop was 10° F or more below the specified temperature. Alternatively, container entry to the retort shall be stopped and the reel shall be restarted to empty the retort. The discharged containers shall be either reprocessed, repacked and reprocessed, or discarded. Both the time at which the reel stopped and the time the retort was used for a still retort process, if so used, shall be marked on the recording chart and entered on the other production records required in this chapter. If the alternative procedure of emptying the retort is followed, the subsequent handling methods used for the containers in the retort at the time of the temperature drop shall be entered on the production records. If the temperature drop was less than 10° F, an authorized emer-

gency still process approved by a qualified person(s) having expert knowledge of thermal processing requirements may be used before restarting the retort reel. Alternatively, container entry to the retort shall be stopped and an authorized emergency agitating process may be used before container entry to the retort is restarted. If any emergency process and procedure is utilized, no containers shall enter the retort during this time and the process and procedures used shall be entered on the production records.

(10) *Critical factors.* The minimum headspace of containers, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. Where the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum (in vacuum-packed products), maximum drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products where deviations from such specifications may affect the scheduled process. Measurements of these critical factors shall be made and recorded at intervals of sufficient frequency to ensure that they are as specified in the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(d) *Equipment and procedures for pressure processing in steam in discontinuous agitating retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer that has a temperature range of not more than 100° F in the processing range on a scale at least 7 inches in length. The scale divisions shall be no more than 2° F. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to ensure their accuracy. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch diameter opening, and shall be equipped with a 1/16-inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeder for external wells shall emit steam continuously during the entire processing period. Thermometers shall be installed where they can be accurately and easily read. A thermometer with a divided mercury column or that deviates more than 1° F from the standard shall be repaired or replaced. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device.* There shall be an accurate temperature recording device for each retort adjusted to agree within 1° F of the known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The chart graduations shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 50° F per inch within a range of 20° F of the processing temperature. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature recorder bulb well shall have a 1/16-inch or larger bleeder opening emitting steam continuously during the processing period.

(3) *Pressure gages.* Each retort shall be equipped with a pressure gage. The gage should be graduated in divisions of 2 pounds or less, should be connected to the retort shell or external well by a short gooseneck tube, and should be not more than 4 inches higher than the gooseneck.The gage should be checked for accuracy at least once a year.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Bleeders.* Bleeders, except those for thermometer wells, shall be ⅛ inch or larger and shall be wide open during the entire process, including the coming-up-time. Bleeders shall be located within approximately 1 foot of each end; additional bleeders shall be located not more than 8 feet apart along the top of the retort. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to ensure removal of condensate. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(6) *Venting and condensate removal.* The air in each retort shall be removed before processing is started. At the time steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort and provision should be made for continuing drainage of condensate during the retort operation.

(7) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The rotational speed shall be adjusted, as necessary, to ensure that the speed is as specified in the scheduled process. The rotational speed as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided.

(8) *Critical factors.* The minimum headspace of containers in each retort load to be processed, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. Where the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum (in vacuum-packed products), maximum drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products where deviations from such specifications may affect the scheduled process. Measurements of these critical factors shall be made and recorded at intervals of sufficient frequency to ensure that they are as specified in the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(e) *Equipment and procedures for pressure processing in water in discontinuous agitating retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer that has a temperature range of not more than 100° F in the processing range on a scale at least 7 inches in length. The scale divisions shall be no more than 2° F. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to ensure their accuracy. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. Thermometers shall be installed where they can be accurately and easily read. A thermometer that has a divided mercury column or that deviates more than 1° F from the standard shall be repaired or replaced. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device.* There shall be an accurate temperature recording device for each retort adjusted to agree within 1° F of the known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The chart graduations shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 50° F per inch within a range of 20° F of the processing temperature. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either

within the retort shell or in a well attached to the shell.

(3) *Pressure gages.* Each retort shall be equipped with a pressure gage. The gage should be graduated in divisions of 2 pounds or less, should be connected to the retort shell or external well by a short gooseneck tube, and should be not more than 4 inches higher than the gooseneck. The gage should be checked for accuracy at least once a year.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The rotational speed shall be adjusted, as necessary, to ensure that the speed is as specified in the scheduled process. The rotational speed as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes shall be provided.

(6) *Air supply and controls.* Means shall be provided for introducing compressed air at the proper pressure and rate. The proper pressure shall be controlled by an automatic pressure control unit. A check valve shall be provided in the air supply line to prevent water from entering the system.

(7) *Critical factors.* The minimum headspace of containers in each retort load to be processed, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. Where the product consistency is specified in the scheduled process the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum (in vacuum-packed products), maximum drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products where deviations from such specifications may affect the scheduled process. Measurements of these critical factors shall be made and recorded at intervals of sufficient frequency to ensure that they are as specified in the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(f) *Equipment and procedures for pressure processing in steam in hydrostatic retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer that has a temperature range of not more than 100° F in the processing range on a scale at least 7 inches in length. The scale divisions shall be no more than 2° F. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to ensure their accuracy. The thermometer shall be located in the steam dome near the steam-water interface. Where the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, a mercury-in-glass thermometer shall be located in each hydrostatic water leg in a position near the bottom automatic recorder so that it can be accurately and easily read. A thermometer that has a divided mercury column or that deviates more than 1° F from the standard shall be repaired or replaced. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device.* There shall be an accurate temperature recording device for each retort adjusted to agree within 1° F of the known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The chart graduations shall not exceed 2° F within a range of 10° F of the processing temperature. Each chart shall have a working scale of not more than 50° F per in. within a range of 20° F of the processing temperature. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either within the steam dome or in a well attached to the dome. Temperature recorder bulb wells shall have a 1/16-inch or large bleeder opening emitting steam continuously during the entire processing period. Additional temperature recorder bulbs shall be installed in the hydrostatic water legs if the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs.

(3) *Recording of temperatures.* Temperatures indicated by the mercury-in-glass thermometer or thermometers shall be entered on a suitable form during processing operations. Temperatures shall be recorded by an accurate automatic recorder or recorders at the following points:

(i) In the steam chamber between the steam-water interface and the lowest container position.

(ii) Near the top and the bottom of each hydrostatic water leg if the scheduled process specifies maintenance of particular temperatures in the legs.

(4) *Venting.* Before the start of processing operations, the retort steam chamber or chambers shall be vented to ensure removal of air.

(5) *Bleeders.* Bleeder openings 1/4-inch or larger shall be located at the end of the steam chamber or chambers opposite from the point of steam entry. Bleeders shall be wide open and shall emit steam continuously during the entire process, including the coming-up-time. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(6) *Retort speed.* The speed of the container conveyor chain shall be specified in the scheduled process and shall be determined and recorded at the start of processing and at intervals of sufficient frequency to ensure that the retort speed is maintained as specified. The speed should be determined and recorded every 4 hours. An automatic device should be used to stop the chain when the temperature drops below that specified in the scheduled process. A means of preventing unauthorized speed changes shall be provided.

(7) *Critical factors.* (i) Where maximum drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Minimum closing machine vacuum (in vacuum-packed products) shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(g) *Aseptic processing and packaging systems* — (1) *Product sterilizer* — (i) *Equipment*—(*a*) *Temperature indicating device.* Each product sterilizer shall be equipped with at least one mercury-in-glass thermometer that has a temperature range of not more than 100° F in the processing range on a scale at least 7 inches in length, or an equivalent temperature indicating device, such as a thermocouple-recorder. The scale divisions or chart graduations of the temperature indicating device shall be no more than 2° F within the range of 10° F of the product sterilization operating range. The device shall be installed in the product at the holding tube outlet between the holding tube and the inlet to the cooler. The temperature indicating device shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to ensure its accuracy. The device shall be installed so that it can be accurately and easily read. A thermometer that has a divided mercury column or a device that deviates more than 1° F from the standard shall be repaired or replaced. The temperature indicating device shall be the reference instrument for indicating the processing temperature.

(*b*) *Temperature recording device.* There shall be an accurate temperature recording device on each product presterilizer. The temperature sensor shall be located in the presterilized product at the holding tube outlet between the holding tube and the inlet of the cooler. The recording device shall be adjusted to agree with a known accurate standard mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The recording device shall not deviate more than 1° F from the standard thermometer; it shall be installed so that it

can be accurately and easily read. The recording chart graduations shall not exceed 2° F within a range of 10° F of the desired product sterilization temperature. The chart shall have a working scale of not more than 50° F per inch within a range of 20° F of the processing temperature.

(c) *Temperature recorder-controller.* An accurate temperature recorder-controller shall be located in the product sterilizer at the final heater outlet. It shall be capable of assuring that the desired product sterilization temperature is maintained. The chart graduations shall not exceed 2° F within a range of 10° F of the desired product sterilization temperature.

(d) *Product-to-product regenerators.* Where a product-to-product regenerator is used to heat the cold unsterilized product entering the sterilizer by means of a heat exchange system. It shall be designed, operated, and controlled so that the pressure of the sterilized product in the regenerator is greater than the pressure of any unsterilized product in the regenerator to ensure that any leakage in the regenerator will be from the sterilized product into the unsterilized product.

(e) *Differential pressure recorder-controller.* Where a product-to-product regenerator is used, there shall be an accurate differential pressure recorder-controller installed on the regenerator. The scale divisions shall not exceed 2 pounds per square inch on a working scale of not more than 20 pounds per square inch per inch. The controller shall be tested for accuracy against a known accurate standard pressure indicator, upon installation and at least once every 3 months of operation thereafter or more frequently as may be necessary to ensure its accuracy. One pressure sensor shall be installed at the sterilized product regenerator outlet, and the other pressure sensor shall be installed at the unsterilized product regenerator inlet.

(f) *Metering pump.* A metering pump shall be located upstream from the holding tube and shall be operated to maintain the required rate of product flow. A means of preventing unauthorized speed changes shall be provided.

(g) *Product holding tube.* The product sterilizing holding tube shall be designed to give continuous holding of every particle of food for at least the minimum holding time specified in the scheduled process. The holding tube shall be designed so that no portion between the product inlet and the product outlet can be heated, and it shall be sloped upward at least 0.25 inch per foot.

(ii) *Operation—(a) Startup.* Prior to the start of aseptic processing operations, the product sterilizer shall be brought to a condition of commercial sterility.

(b) *Temperature drop in product sterilizing holding tube.* When product temperature in the holding tube drops below the temperature specified in the scheduled process, the product holding tube and any further system portions affected shall be returned to a condition of commercial sterility before flow is resumed to the filler.

(c) *Loss of proper pressures in the regenerator.* Where a regenerator is used the product may lose sterility whenever the pressure of sterilized product in the regenerator is less than 1 lb. per square in. greater than the pressure of unsterilized product in the regenerator. Product flow to the filler shall not be resumed until the cause of the improper pressure relationships in the regenerator has been corrected and the affected system(s) has been returned to a condition of commercial sterility.

(d) *Records.* Readings at the following points shall be observed and recorded at the start of aseptic packaging operations and at intervals of sufficient frequency to ensure that these values are as specified in the scheduled process: Temperature indicating device in holding tube outlet; temperature recorder in holding tube outlet; temperature recorder-controller at final heater outlet; differential pressure recorder-controller, if a product-to-product regenerator is used; and product flow rate as established by the meering pump or as determined by filling and closing rates. Such measurements and recordings should be made at intervals not to exceed 1 hour.

(2) *Container sterilizing, filling, and closing operation*—(i) *Equipment—(a) Recording device.* The container and closure sterilization system and product filling and closing system shall be instrumented to show that commercial sterility is being achieved. Automatic recording devices shall be used to record, where applicable, the sterilization media flow rates and/or temperatures. Where a batch system is used for container sterilization, the sterilization conditions shall be recorded.

(b) *Timing method(s).* A method(s) shall be used either to give the retention time of containers, and closures if applicable, in the sterilizing environment as specified in the scheduled process, or to control the sterilization cycle at the rate as specified in the scheduled process. A means of preventing unauthorized speed changes shall be provided.

(ii) *Operation—(a) Startup.* Prior to the start of packaging operations, both the container and closure sterilizing system and the product filling and closing system shall be brought to a condition of commercial sterility.

(b) *Loss of sterility.* In the event of loss of sterility, the system(s) shall be returned to a condition of commercial sterility before resuming packaging operations.

(c) *Records.* Observations and measurements of operating conditions shall be made and recorded at intervals of sufficient frequency to ensure that commercial sterility of the food product is being achieved; such measurements shall include the sterilization media flow rates and/or temperatures, the container and closure rates (if applicable) through the sterilizing system, and the sterilization conditions if a batch system is used for container sterilization. The measurements and recordings should be made at intervals not to exceed 1 hour.

(3) *Incubation.* Incubation tests shall be conducted on a representative sample of containers of product from each code; records of the tests shall be maintained.

(h) *Equipment and procedures for flame sterilizers.* The container conveyor speed shall be specified in the scheduled process. The container conveyor speed shall be measured and recorded at the start of operations and at intervals of sufficient frequency to ensure that the conveyor speed is as specified in the scheduled process. Such measurements and recordings should be done at 1-hour intervals. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on the conveyor shall be provided. The surface temperature of at least one container from each conveyor channel shall be measured and recorded at the end of the holding period at intervals of sufficient frequency to ensure that the temperatures specified in the scheduled process are maintained. Such measurements and recordings should be done at intervals not to exceed 15 minutes.

(i) *New systems.* The development of new systems for the thermal processing of low-acid foods in hermetically sealed containers shall conform to the applicable requirements of this part and shall ensure that the methods and controls used for the manufacture, processing, and/or packing of such foods are operated or administered in a manner adequate to achieve commercial sterility.

Subpart D—Control of Components, Food Product Containers, Closures, and In-Process Materials

§ 113.60 Containers.

(a) *Closures.* Regular observations shall be maintained during production runs for gross closure defects. Any such defects shall be recorded, and corrective action shall be taken and recorded. At intervals of sufficient frequency to ensure proper closure, the operator, closure supervisor, or other qualified container closure inspection person shall visually examine either the top seam of a can randomly selected from each seaming head or the closure of any other type of container being used, and shall record his observations. Such measurements and recordings shoud be made at intervals not to exceed 30 minutes. Additional visual closure inspections shall be made immediately following a jam in a closure machine, after closing machine adjustment, or after startup of a machine following a prolonged shutdown. All pertinent observations shall be recorded. Where irregularities are found, the corrective action shall be recorded.

(1) Teardown examinations for double seam cans shall .be performed by a qualified individual and the results therefrom shall be recorded at intervals of sufficient frequency on enough containers from each seaming station to ensure maintenance of seam integrity. Such examinations and recordings should be made at intervals not to exceed 4 hours. The results of the teardown examinations shall be recorded and the corrective action taken, if any, shall be noted.

(i) Required and optional can seam measurements:

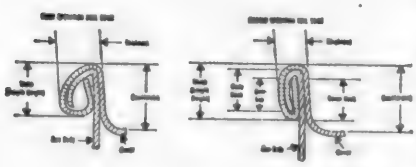
(*a*) Micrometer measurement system:

Required	*Optional*
Cover hook.	Overlap (by calculation).
Body hook.	Countersink.
Width (length, height).	
Tightness (observation for wrinkle).	Thickness.

(*b*) Seam scope or projector:

Required	*Optional*
Body hook.	Width (length, height).
Overlap.	Cover hook.
Tightness (observation for wrinkle).	Countersink.
	Thickness.

(*c*) Can double seam terminology:



(ii) Two measurements at different locations, excluding the side seam, shall be made for each double seam characteristic if a seam scope or seam projector is used. When a micrometer is used, three measurements shall be made at points approximately 120° apart, excluding the side seam.

(iii) Overlap length can be calculated by the following formula:

The theoretical overlap length = CH + BH + T − W

where

CH = cover hook
BH = body hook
T = cover thickness, and
W = seam width (height, length)

(2) For closures other than double seams, appropriate detailed inspections and tests shall be conducted by qualified personnel at intervals of sufficient frequency to ensure proper closing machine performance and consistently reliable hermetic seal production. Records of such tests shall be maintained.

(b) *Cooling.* Container cooling water should be chlorinated as necessary by the processor so that there is a measurable free chlorine residual at the water discharge point of the container cooler. Other safe chemical or physical treatment which is equivalent to chlorination in its bactericidal effect may be used. Where pressure cooling is utilized, adequate pressure should be maintained for a time sufficient to prevent permanent distortion of the container.

(c) *Coding.* Each hermetically sealed container of low-acid processed food shall be marked with an identifying code which shall be permanently visible to the naked eye. Where the container does not permit the code to be embossed or inked, the label may be legibly perforated or otherwise marked, provided that the label is securely affixed to the product container. The required identification shall identify in code the establishment where packed, the product contained therein, the year packed, the day packed, and the period during which packed. The packing period code shall be changed with sufficient frequency to enable ready identification of lots during their sale and distribution. Codes may be changed on the basis of one of the following: Intervals of every 4 to 5 hours; personnel shift changes; or batches, provided the containers comprising such batch do not extend over a period of more than one personnel shift.

(d) *Postprocess handling.* Where cans are handled on belt conveyors, such conveyors should be so constructed as to minimize contact by the belt with the double seam, i.e., cans should not be rolled on the double seam. All worn and frayed belting, can retarders, cushions, etc. should be replaced with new nonporous material. All tracks and belts which come into contact with the can seams should be thoroughly scrubbed and sanitized at intervals of sufficient frequency to avoid product contamination. Automatic equipment used in handling filled containers should be so designed and operated in such a manner as to preserve the can seam or other container closure integrity.

Subpart E—Production and Process Controls

§ 113.81 Product preparation.

(a) Incoming raw materials, ingredients, and packaging components should be inspected upon receipt to ensure that they are suitable for processing. Raw materials should be received in an area separate from the processing areas. Prior to being placed in inventory, ingredients susceptible to microbiological contamination which would render them unsuitable for processing either should be examined for microbiological condition or should be received under a supplier's guarantee that they are of a microbiological condition suitable for use in processing low-acids foods. Products should be held prior to processing in such a manner as to minimize growth of microorganisms.

(b) Blanching by heat, when required in the preparation of food for canning, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent processing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by cleaning. Where the blanched food product is washed prior to filling, potable water should be used.

(c) The filling of containers, either mechanically or by hand, shall be controlled so as to ensure that the filling requirements specified in the scheduled process are met.

(d) The exhausting of containers for the removal of air shall be controlled so as to meet the conditions for which the process was designed. This may be done by heat exhausting, mechanical exhausting, hot brining, or steam injection.

(e) When normally low-acid fruits, vegetables, or vegetable products require sufficient acidification to permit safe processing at low temperatures, such as in boiling water, there shall be careful supervision to ensure that the equilibrium pH of the finished product meets that of the scheduled process.

§ 113.83 Establishing scheduled processes.

Scheduled processes for low-acid foods shall be established by qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations. The type, range, and combination of variations encountered in commercial production shall be adequately provided for in establishing the scheduled process. Critical factors which may affect the scheduled process (e.g., minimum headspace, consistency, maximum drained weight, etc.) shall be specified in the scheduled process. Acceptable scientific methods of establishing heat sterilization processes shall include, where necessary, but not be limited to microbial thermal death time data, process calculations based on product heat penetration data, inoculated packs, and incubation tests. Product heat penetration data may be mathematically converted in calculating processes for different container sizes and thermal processing temperatures. If incubation tests are necessary, they shall include containers from test trials and from actual commercial production runs during the period of instituting the process. The incubation tests for establishing scheduled processes should include the containers from the test trials and a number of containers from each of four or more actual commercial production runs. The number of containers from actual commercial production runs should be determined on the basis of recognized scientific methods to be of a size sufficient to ensure the adequacy of the process. Complete records covering all aspects of the establishment of the process and associated incubation tests shall be prepared and shall be permanently retained by the person or organization making the determination.

§ 113.87 Operations in the thermal processing room.

(a) Scheduled processes and venting procedures to be used for each product and container size being packed shall either be posted in a conspicuous place near the processing equipment or shall be made readily available to the retort or processing system operator and any duly authorized employee of the Food and Drug Administration.

(b) All retort baskets, trucks, cars, or crates containing unretorted food product, or some of the containers on the top of each basket, shall be plainly and conspicuously marked with a heat sensitive indicator, or by other effective means, which will visually indicate to thermal processing personnel whether or not each such unit has been retorted.

(c) The initial temperature of the contents of the containers to be processed shall be determined and recorded with sufficient frequency to ensure that the temperature of the product is no lower than the minimum initial temperature specified in the scheduled process.

(d) Timing devices used in recording thermal process time information shall be accurate to the extent needed to ensure that the processing time specified in the scheduled process is achieved. Pocket or wrist watches shall not be considered satisfactory for timing purposes.

(e) For continuous agitating retorts, the condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. A record shall be kept to show how it is functioning.

§ 113.89 Deviations in processing.

Whenever any process is less than the scheduled process for any low-acid food or container system as disclosed from records, by processor check, or otherwise, the commercial processor of such low-acid food shall either fully reprocess that portion of the production involved, keeping full records of the reprocessing conditions or, alternatively, shall set aside that portion of the production involved for further evaluation as to any potential public health significance. Such evaluation shall be made by a competent processing authority and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health. Unless such evaluation demonstrates that the product had been given a thermal process that rendered it free of microorganisms of potential public health significance, the product set aside either shall be fully reprocessed to render it commercially sterile or it shall be destroyed. A record shall be made of the evaluation procedures used and the results. Either upon completion of full reprocessing and the attainment of commercial sterility or after the determination that no significant potential for public health hazard exists, that portion of the production involved may be shipped in normal distribution. Otherwise, the portion of the production involved shall be destroyed.

Subpart F—Records and Reports

§ 113.100 Records.

(a) Processing and production information shall be entered by the retort or processing system operator, or other designated person, on forms which shall include the product, the code number, the retort or processing system number, the size of container, the approximate number of containers per coding interval, the minimum initial temperature, the actual processing time and temperature, the mercury-in-glass and recording thermometer readings, and other appropriate processing data. Closing machine vacuum (in vacuum-packed products), maximum drained weight, or other critical factors specified in the scheduled process shall also be recorded. In addition, the following records shall be maintained:

(1) *Still retorts.* Time steam on; time temperature up to processing temperature; time steam off; venting time and/or temperature to which vented (as applicable).

(2) *Agitating retorts.* Functioning of condensate bleeder; retort speed; and, where specified in the scheduled process, headspace, consistency, maximum drained weight, minimum net weight, and percent solids.

(3) *Hydrostatic retorts.* The temperature in the steam chamber between the steam-water interface and the lowest container position; speed of the container conveyor chain; and, where the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, the temperatures near the top and the bottom of each hydrostatic water leg.

(4) *Aseptic processing and packaging systems.* Product temperature in the holding tube outlet as indicated by the temperature indicating device and the temperature recorder; product temperature in the final heater outlet as indicated by the temperature recorder-controller; differential pressure as indicated by the differential pressure recorder-controller, if a product-to-product regenerator is used; product flow rate, as determined by the metering pump or by filling and closing rates; sterilization media flow rate and/or temperature; retention time of containers, and closures where applicable, in the sterilizing equipment; and, where a batch system is used for container and/or closure sterilization, sterilization cycle times and temperatures.

(5) *Flame sterilizers.* Container conveyor speed; surface temperature at the end of the holding period; nature of container.

(b) Recording thermometer charts shall be identified by date, and other data as necessary, so they can be correlated with the written record of lots processed. Each entry on the record shall be made by the retort or processing system operator, or other designated person, at the time the specific retort or processing system condition or operation occurs, and the retort or processing system operator or such designated person shall sign or initial each record form. Not later than 1 working day after the actual process, and prior to shipment or release for distribution, a representative of plant management who is qualified by suitable training or experience shall review all processing and production records for completeness and to ensure that the product received the scheduled process. The records, including the recording thermometer chart(s), shall be signed or initialed by the person conducting the review.

(c) Written records of all container closure examinations shall specify the product code, the date and time of container closure inspections, the measurements obtained, and all corrective actions taken. Records shall be signed or initialed by the container closure inspector and shall be reviewed by management with sufficient frequency to assure that the containers are hermetically sealed.

(d) Copies of all records provided for in this part except those required under § 113.83 establishing scheduled processes, shall be retained at the processing plant for a period of not less than one year, and at the processing plant or other reasonably accessible location for an additional two years. If during the first year of the three-year record retention period the processing plant is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack.

PART 118—CACAO PRODUCTS AND CONFECTIONERY

Subpart A—General Provisions

Sec.
118.1 Current good manufacturing practice.
118.3 Definitions.

Subpart B—Buildings and Facilities

118.20 Plants and grounds.
118.35 Sanitation facilities.
118.37 Sanitary operations.

Subpart C—Equipment

118.40 Equipment and procedures.

Subpart D—[Reserved]

Subpart E—Production and Process Controls

118.80 Processes and controls.

Subpart F—Records and Reports

118.100 Records.

AUTHORITY: Secs. 402(a)(4), 409, 701(a), 52 Stat. 1046, 1055, 72 Stat. 1785–1788 (21 U.S.C. 342(a)(4), 348, 371(a)).

Subpart A—General Provisions

§ 118.1 Current good manufacturing practice.

(a) The criteria and definitions in Part 110 of this chapter shall apply in determining whether the facilities, methods, practices, and controls used for the manufacture, processing, packing, or holding of cacao products and confectionery are in conformance with and are operated or administered in conformity with good manufacturing practices to produce, under sanitary conditions, food for human consumption.

(b) The criteria in §§ 118.20, 118.35, 118.37, 118.40, 118.80, and 118.100 set forth additional standards to be applied in evaluating the methods and procedures used in the manufacture, processing, packaging, packing, or holding of cacao products and confectionery.

(c) Pertinent criteria from Part 110 of this chapter have been incorporated into §§ 118.20, 118.35, 118.37, 118.40, 118.80, and 118.100 to emphasize critical control points in the manufacture, processing, packaging, packing, or holding of cacao products and confectionery.

§ 118.3 Definitions.

For the purposes of this part, the following definitions apply:

(a) "Cacao products" means any form of chocolate, chocolate product, cocoa, or

cocoa product. Such foods include but are not limited to cacao nibs, sweet chocolate, milk chocolate, other foods standardized by Part 163 of this chapter, and chocolate sirup. They do not include the raw cacao bean, extracts, flavoring derived from such extracts, and chocolate- or cocoa-flavored foods.

(b) "Confectionery" means candy and other food products made with sweeteners, and frequently prepared with colorings, flavorings, milk products, cacao products, nuts, fruits, starches, and other materials. Such foods include but are not limited to frostings, toppings, and cake decorations. They do not include chewing gum, sauces, sirups, jellies, jams, preserves, cakes, or cookies.

(c) "Lot" means a collection of primary containers or units of the same size, type and style, containing finished product produced under conditions as nearly uniform as possible, designated by a common container code or marking, and, in any event no more than a day's production.

(d) "Return" means clean, wholesome product(s) returned to the manufacturer for reprocessing for reasons other than insanitary conditions and which is suitable for use as food.

(e) "Rework" means clean, wholesome product(s) removed from processing for reasons other than insanitary conditions and which is suitable for reprocessing and for use as food.

(f) "Shall" refers to mandatory requirements and "should" refers to recommended or advisory procedures or equipment.

(g) "Waste" means product rejected due to adulteration that renders it unsuitable for use as human food.

Subpart B—Buildings and Facilities

§ 118.20 Plants and grounds.

Effective measures shall be taken to prevent contamination of products, raw materials, or packaging materials with microorganisms, chemicals, filth, or other extraneous material. This may be accomplished by separating the following operations by partition, location, air flow, enclosed systems, or other effective means:

(a) Receiving.

(b) Raw material storage.

(c) Cacao bean cleaning, roasting, cooling, cracking, and fanning.

(d) Cacao product milling, pressing, mixing, refining, conching, tempering, and molding.

(e) Pulverizing or separating of cocoa, and other dusty operations.

(f) Cacao product and confectionery processing.

(g) Portable equipment and utensil cleaning and sanitizing.

(h) Packaging and packing.

(i) Finished product storage and shipping.

§ 118.35 Sanitation facilities.

(a) Adequate and readily accessible hand washing and sanitizing facilities shall be provided in the plant for employees who may handle unprotected food, unprotected packaging materials, and food-contact surfaces. Such facilities shall be furnished with running water at a suitable temperature for hand washing, effective hand cleaning and sanitizing preparations, sanitary towel service or suitable drying devices, and, where appropriate, refuse receptacles constructed and maintained in a manner to prevent product contamination. These facilities should also be equipped wtih water control valves so designed and constructed as to prevent recontamination of clean, sanitized hands.

(b) Readily understandable signs directing employees handling unprotected food, unprotected packaging materials, or food-contact surfaces, to wash and sanitize their hands before starting work, after each absence from post of duty, and when their hands may have become soiled or contaminated shall be conspicuously posted in the processing room(s) and in all other areas where employees may handle such materials and surfaces.

(c) Management shall maintain sufficient control to ensure that employees handling unprotected food, unprotected packaging materials, or food-contact surfaces wash and sanitize their hands before starting work, after each absence from post of duty, and when their hands may have become soiled or contaminated.

§ 118.37 Sanitary operations.

(a) Cleaning and sanitizing of utensils and equipment shall be carried out in such a manner as to prevent raw material, packaging material, or product contamination.

(b) Food-contact surfaces of equipment used for processing or holding low moisture raw materials or products such as chocolate, fats and oils, liquid nutritive sweeteners, peanut butter, and similar materials which are not conducive to microbial growth shall be maintained in a sanitary condition. When wet cleaning of such equipment may cause conditions conducive to microbial growth, other appropriate cleaning methods shall be utilized to prevent product contamination.

(c) Poisonous or dangerous cleaning compounds, sanitizing agents, and pesticide chemicals shall be applied, stored, and held in such a manner as to prevent food or packaging material contamination. These materials shall be identified and used only in such manner and under such conditions as will be safe for their intended use. Any applicable regulations promulgated by the Environmental Protection Agency for the application, use, or holding of such material shall be followed.

Subpart C—Equipment

§ 118.40 Equipment and procedures.

(a) Food-contact surfaces shall be corrosion-free and made of nontoxic material that will not crack or disintegrate in normal operation and will withstand the environment of its intended use and the action of food ingredients, cleaning compounds, and sanitizing agents. All food-contact surfaces shall be maintained to prevent product contamination and shall be in compliance with section 409 of the act (21 U.S.C. 348) as it pertains to indirect food additives.

(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to prevent microbiological contamination in places where dirt or organic material might accumulate.

(c) Nonfood-contact surfaces of equipment shall be so constructed that they can be kept in a clean condition.

(d) Regulating and/or recording controls, thermometers, other temperature measuring devices, and temperature recording devices on equipment used to pasteurize raw materials or products shall be accurate and effective for their designated uses. The accuracy of temperature controlling, measuring, and recording devices on equipment used to control or prevent undesirable microbial growth in raw materials or finished products shall be within ±2° F.

(e) Each freezer and cold storage compartment used for storing or holding raw materials or products capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature measuring device, or temperature recording device so installed as to show accurately the temperature within the compartment, and should be fitted with an automatic control for regulating temperature or an automatic alarm system to indicate a significant temperature change in a manual operation.

(f) Cooling tunnels on processing lines shall have access doors or other provisions to permit cleaning of the interior.

Subpart D—[Reserved]

Subpart E—Production and Process Controls

§ 118.80 Processes and controls.

The manufacturer shall employ appropriate quality control procedures and treatments to ensure that raw materials and finished products are wholesome and fit for food, that packaging materials are safe and suitable and that all of the foregoing materials are otherwise in compliance with the Federal Food, Drug, and Cosmetic Act.

(a) *Handling of raw materials.* (1) Milk and milk products shall have been pasteurized before use, and egg products shall have been pasteurized or otherwise treated to destroy viable Salmonella microorganisms before use, or these materials (i.e., milk, milk products and egg products) shall be pasteurized or otherwise treated during processing operations to destroy pathogenic microorganisms. The manufacturer shall ensure that gelatin, dried coconut, nuts, and other raw materials susceptible to contamination by pathogenic microorganisms are free of such microorganisms before these materials are incorporated into finished products unless these materials are pasteurized or otherwise treated before or during processing operations to destroy pathogenic microorganisms. Compliance with this requirement may be accomplished by purchasing these materials under a supplier's guarantee or certification, or verified by analyzing these materials for pathogenic microorganisms.

(2) The manufacturer shall ensure that peanuts, Brazil nuts, pistachio nuts,

filberts, walnuts, almonds, pecans, corn meal, and other raw materials susceptible to aflatoxin contamination comply with current Food and Drug Administration regulations, guidelines, and action levels for poisonous or deleterious substances before these materials are incorporated into finished products. Compliance with this requirement may be accomplished by purchasing these materials under a supplier's guarantee or certification, or verified by analyzing these materials for aflatoxins.

(3) The manufacturer shall ensure that nuts, raisins, cacao beans, spices, rework, return, and other raw materials susceptible to infestation or contamination by animals, birds, vermin, microorganisms, or extraneous material comply with current Food and Drug Administration regulations, guidelines, and action levels for natural or unavoidable defects before these materials are incorporated into finished products. Compliance with this requirement may be verified by examining these materials for infestation and contamination.

(b) *Storing and holding of raw materials.* Raw materials shall be held in containers so designed and constructed as to prevent raw material contamination. Raw materials and packaging materials shall be held at such temperature and relative humidity and in such a manner as to prevent their adulteration due to contamination or decomposition.

(1) Materials capable of supporting growth of pathogenic microorganisms shall be stored at a temperature below 40° F or above 140° F, except for such period of time actually required for the processing involved and which does not affect the wholesomeness of the raw materials.

(2) Frozen materials shall be kept frozen and should be stored at a temperature of 0° F or below.

(3) Liquid sugars shall be held in such a manner as to prevent microbial growth or any other direct or indirect contamination. Storage tanks for liquid sugars shall have filtered air-intake vents.

(4) Liquid mixtures containing egg products or other perishable materials and capable of supporting growth of pathogenic microorganisms shall be held in such a manner as to preclude the growth of these microorganisms or shall be processed in such a manner as to destroy these microorganisms. This may be accomplished by:

(i) Maintaining the mixtures at a temperature below 40° F after removal from storage and disposing of the unused portion at least every 12 hours during operations and at the end of the day's operation; or

(ii) Maintaining the mixture at a temperature below 50° F after removal from storage and disposing of the unused portion at least every 4 hours during operations and at the end of the day's operation; or

(iii) Pasteurizing or otherwise treating the mixtures during processing operations to destroy pathogenic microorganisms.

(c) *Processing operations.* (1) Frozen egg products shall be defrosted in a sanitary manner and by such methods that their wholesomeness is not adversely affected. This may be accomplished by defrosting at a temperature of 40° F or below, or by defrosting at a temperature above 40° F for a period of time not exceeding 24 hours: *Provided,* That the temperature in any part of the defrosted liquid does not exceed 50° F.

(2) Processes intended to pasteurize or otherwise treat materials to destroy pathogenic microorganisms shall be scientifically determined to be adequate under the conditions of manufacture for a given product to ensure destruction of such microorganisms.

(3) Rework and return shall be considered as raw materials. They shall be held in properly identified containers in a manner to prevent product contamination.

(4) Waste shall not contribute to direct or indirect product contamination. This may be accomplished by holding the waste in properly identified containers and removing it from the processing area daily.

(5) Effective measures shall be taken to prevent cross contamination between raw materials and finished products or between refuse and these materials. When any of these materials are unprotected they shall not be handled simultaneously in a receiving, loading, or shipping area. Raw materials and products transported by conveyor shall be protected against contamination from extraneous material.

(6) Equipment, containers, and utensils used to convey, process, hold or store raw materials or products shall be handled during processing or storage in such a manner as to prevent raw material or product contamination.

(7) Effective measures shall be taken to prevent the inclusion of metal or other extraneous material in finished products. This may be accomplished by using suitable equipment such as sieves, magnets, electronic metal detectors, or by other effective means.

(8) Effective measures shall be taken to remove extraneous material from molding starch before it is reused in molding operations. This may be accomplished by passing the starch through a sieve and a metal trap or by otherwise treating it to remove extraneous material.

(9) The cooling and winnowing of roasted cacao beans and the processing and storage of cocoa nibs shall be carried out in such a manner as to prevent product contamination.

(10) Cacao bean shell, dust, and other residue particles resulting from cracking operations shall be handled and held in such a manner as to prevent product contamination.

(11) Adulterated materials shall be disposed of in such a manner as to prevent raw material, rework, return, or finished product contamination, or shall be reconditioned, if feasible, and then reexamined and found to be wholesome before being incorporated into finished products.

(d) *Coding.* Permanently legible code marks shall be placed at a readily visible location on each shipping container or they shall be placed on each finished product package delivered or displayed to retail purchasers and be visible on the unopened package. The code marks may be placed in both locations if desired by the manufacturer. Such marks shall identify at least the plant where packed and the product lot or packaging lot.

(e) *Warehousing and distribution.* Finished products shall be handled in storage, during shipment, and while being held for sale in such a manner as to prevent product contamination. Transportation equipment, warehouses, and other facilities used for storing, holding, or transporting finished products shall be of such design and construction as to prevent contamination or adulteration of the products. Such facilities and equipment shall be free of vermin or other objectionable conditions.

Subpart F—Records and Reports

§ 118.100 Records.

(a) Records shall be maintained of the results of examinations of raw materials, packaging materials, and finished products. Suppliers' guarantees or certifications that verify compliance with Food and Drug Administration regulations and guidelines shall be retained.

(b) Processing and production records covering processes intended to pasteurize or otherwise treat materials to destroy pathogenic microorganisms shall be maintained, and shall contain sufficient information to permit a public health evaluation of the processes.

(c) Records shall be maintained to identify the initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise rendered unfit for their intended use.

(d) The records required by paragraphs (a), (b), and (c) of this section shall be retained for a period of time that exceeds the shelf life of the finished product, except that they need not be retained more than 2 years.

PART 122—SMOKED AND SMOKE-FLAVORED FISH

Subpart A—General Provisions

Sec.
122.1 Current good manufacturing practice.
122.3 Definitions.

Subpart B—Buildings and Facilities

122.20 Plants and grounds.
122.35 Sanitary facilities.
122.37 Sanitary operations.

Subpart C—Equipment

122.40 Equipment and procedures.

Subpart D—[Reserved]

Subpart E—Production and Process Controls

122.80 Processes and controls.

AUTHORITY: Secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a)(4), 371(a)).

Subpart A—General Provisions

§ 122.1 Current good manufacturing practice.

(a) The criteria in Part 110 of this chapter shall apply in determining whether the facilities, methods, practices, and controls used for the manufacture, processing, packing, or holding of fish and seafood products are in conformance with and are operated or administered in conformity with good manufacturing practice to produce, under sanitary conditions, food for human consumption.

(b) The criteria in this part set forth additional requirements for the hot-process smoked or hot-process smoke-flavored fish industry.

§ 122.3 Definitions.

For the purposes of this part, the following definitions apply:

(a) "Smoked fish" means any fish that is prepared by treating it with salt (sodium chloride) and then subjecting it to the direct action of smoke from burning wood, sawdust, or similar material.

(b) "Smoke-flavored fish" means any fish that is prepared by treating it with salt (sodium chloride) and then imparting to it the flavor of smoke by other than the direct action of smoke. This paragraph does not alter the labeling requirements under § 101.22 of this chapter.

(c) "Loin muscle" means the longitudinal quarter of the great lateral muscle freed from skin, scales, visible blood clots, bones, gills, and viscera and from the nonstriated part of such muscle, which part is known anatomically as the median superficial muscle.

(d) "Water phase salt" means the percent salt (sodium chloride) in the finished product as determined by the method described in sections 18.009 and 18.010 of the "Official Methods of Analysis of the Association of Agricultural Chemists," 10th edition, page 273 (1965), multiplied by 100 and divided by the percent salt (sodium chloride) plus the percent moisture in the finished product as determined by the method described in section 18.006 of said edition.

(e) "Hot-process smoked or hot-process smoke-flavored fish" means the finished food prepared by subjecting forms of smoked fish referred to in paragraphs (a) and (b) of this section to heat as prescribed in § 122.80(d).

Subpart B—Buildings and Facilities

§ 122.20 Plants and grounds.

(a) Unloading platforms shall be:

(1) Made of readily cleanable material.

(2) Equipped with drainage facilities adequate to accommodate all seepage and wash water.

(b) The following processes should be carried out in separate rooms or facilities, and the interior walls separating these processes should extend from floor to ceiling and contain only necessary openings (such as for conveyors and doorways):

(1) Receiving or shipping.

(2) Storage of raw fish.

(3) Presmoking operations (thawing, dressing, brining, etc.).

(4) Drying and smoking.

(c) The following processes shall be carried out in separate rooms or facilities, and the interior walls separating these processes shall extend from floor to ceiling and contain only necessary openings (such as for conveyors and doorways):

(1) Cooling and packing.

(2) Storage of final product.

(d) The product shall be so processed as to prevent contamination by exposure to areas, utensils, or equipment, involved in earlier processing steps, refuse, or other objectionable areas.

§ 122.35 Sanitary facilities.

(a) Adequate hand-washing and sanitizing facilities shall be located in the processing room(s) or in one area easily accessible from the processing room(s).

(b) Readily understandable signs directing employees to wash and sanitize their hands after each absence from post of duty shall be conspicuously posted in the processing room(s) and elsewhere in the plant as conditions require.

(c) Offal shall be placed in suitable covered containers for removal at least once a day, or more frequently if necessary, or shall be removed by conveyors or chutes. Offal, debris, or refuse from any source whatever shall not be allowed to accumulate in or about the plant.

§ 122.37 Sanitary operations.

(a) Before beginning the day's operation, all utensils and product-contact surfaces of equipment to be used for the day's operation shall be rinsed and sanitized.

(b) Containers used to convey or store fish shall not be nested while they contain fish or otherwise handled during processing or storage in a manner conducive to direct or indirect contamination of their contents.

(c) Cleaning and sanitizing of utensils and portable equipment should be conducted in an area set aside for these purposes and shall be carried out in such a manner as to prevent contamination of the fish or fish products.

Subpart C—Equipment

§ 122.40 Equipment and procedures.

(a) All food-contact surfaces (tanks, belts, tables, utensils, and other equipment) shall be made of readily cleanable materials.

(b) Metal seams shall be smoothly soldered, welded, or bonded.

(c) Each freezer and cold storage compartment used for the product shall be fitted with at least the following:

(1) An automatic control for regulating temperature.

(2) An indicating thermometer so installed as to show accurately the temperature within the compartment.

(3) A recording thermometer so installed as to indicate accurately at all times the temperature within the compartment.

(d) Thermometers or other temperature-measuring devices shall have an accuracy of ±2° F.

Subpart D—[Reserved]

Subpart E—Production and Process Controls

§ 122.80 Processes and controls.

(a) *Raw materials.* (1) Fresh fish received shall be inspected and adequately washed before processing. Only sound, wholesome fish free from adulteration and organoleptically detectable spoilage shall be processed.

(2) Every lot of fish that has been partially processed in another plant, including frozen fish, shall be adequately inspected, and only clean, wholesome fish shall be processed.

(3) Fresh or partially processed fish, except those to be immediately processed, shall be iced or otherwise refrigerated to an internal temperature of 38° F or below upon receipt and shall be maintained at that temperature until the fish are to be processed.

(4) All fish received in a frozen state shall be either thawed promptly and processed, or stored at a temperature that will maintain it in a frozen state.

(b) *Defrosting of frozen fish.* (1) Defrosting shall be carried out in a sanitary manner and by such methods that the wholesomeness of the fish is not adversely affected. Frozen fish shall be defrosted:

(i) In air at 45° F or below until other than hard frozen; or

(ii) In air so that the temperature in any part of the fish does not exceed 45° F; or

(iii) In a continuous water-overflow thaw tank or spray system in such a manner that the temperature in any part of the fish does not exceed 45° F.

(2) When a thaw tank is used, fish should not remain in the tank longer than one-half hour after they are completely defrosted.

(3) Fish entering the thaw tanks shall be free of exterior packaging material and substantially free of liner material.

(4) After thawing, fish shall be washed thoroughly with a vigorous water spray or a continuous waterflow system.

(c) *Presmoking operation.* (1) Evisceration of fish shall be performed with minimum disturbance of intestinal tract contents. Removal of viscera shall be complete.

(2) After the evisceration process, the fish (including the body cavity) shall be thoroughly washed with a vigorous water spray or a continuous waterflow system.

(3) All fish shall be dry-salted at a temperature not to exceed 38° F throughout the fish, or shall be brined in such a manner that the temperature of the fish and the brine:

(i) Does not exceed 60° F at the start of brining, and

(ii) If between 38° F and 50° F at the start of brining, is continuously lowered to 38° F or below within 12 hours, and

(iii) If between 50° F and 60° F at the start of brining, is continuously lowered to 50° F or below within 2 hours and to 38° F or below within the following 10 hours, and

(iv) Does not rise above 38° F after reaching that temperature or below

either prior to or during the brining operation.

(4) Hot-process smoked or hot-process smoke-flavored fish shall be brined in such a manner that the final salt (sodium chloride) content of the loin muscle of the finished product, expressed as percent in the water phase of the loin muscle, shall not be less than:

(i) 3.5 percent if heat-processed as prescribed under paragraph (d)(2)(i) of this section; or

(ii) 5.0 percent if heat-processed as prescribed under paragraph (d)(2)(ii) of this section.

(5) Fish shall be rinsed with fresh water after brining.

(d) *Heating, cooking, smoking operation.* (1) A point-sensitive, continuous temperature-recording device shall be used to monitor both the internal temperature of the fish and the ambient temperature within the oven. Each recording-device record shall be identified as to the specific oven load and date processed.

(2) Hot-process smoked or hot-process smoke-flavored fish shall be heated by a controlled heat process that provides a monitoring system positioned in as many strategic locations in the oven as necessary to assure a continuous temperature throughout each fish of:

(i) Not less than 180° F for a minimum of 30 minutes for hot-process smoked or hot-process smoke-flavored fish which have been brined to contain 3.5 percent water phase salt in the finished product as prescribed in paragraph (c)(4)(i) of this section, except that smoked chub containing sodium nitrite as provided for in § 172.177 of this chapter shall be processed in accordance with that section; or

(ii) Not less than 150° F for a minimum of 30 minutes for hot-process smoked or hot-process smoke-flavored fish which have been brined to contain 5.0 percent water phase salt in the finished product as prescribed in paragraph (c)(4)(ii) of this section.

(e) *Packing.* (1) The finished product shall be handled only with clean, sanitized hands, gloves, or utensils.

(2) Manual manipulation of the finished product shall be kept to a minimum.

(3) The finished product shall be cooled to a temperature of 50° F or below within 3 hours after cooking and further cooled to a temperature of 38° F or below within 12 hours after cooking, and this temperature shall be maintained during all subsequent storage and distribution.

(4) The shipping containers, retail packages, and shipping records shall indicate by appropriate labeling the perishable nature of the product and shall specify that the product shall be shipped, stored, and/or held for sale at 38° F or below until consumed.

(5) Permanently legible code marks shall be placed on the outer layer of every finished product package and master carton. Such marks shall identify at least the plant where packed, the date of packing, and the oven load. Records shall be so maintained as to provide positive identification (i) of the process procedures used for the manufacture of hot-process smoked or hot-process smoke-flavored fish and (ii) of the distribution of the finished product.

(f) *Testing.* (1) Microbiological examination of in-line and finished product samples should be conducted with sufficient frequency to assure that processing steps and sanitary procedures are adequate.

(2) The finished product shall be analyzed chemically with sufficient frequency to assure that the required salinity is obtained in every fish and that other chemical additives are present at authorized levels.

PART 123—FROZEN RAW BREADED SHRIMP

Subpart A—General Provisions

Sec.
123.1 Current good manufacturing practice.
123.3 Definitions.

Subpart B—Buildings and Facilities

123.20 Plants and grounds.
123.35 Sanitary facilities and controls.
123.37 Sanitary operations.

Subpart C—Equipment

123.40 Equipment and procedures.

Subpart D—[Reserved]

Subpart E—Production and Process Controls

123.80 Processes and controls.

AUTHORITY: Secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a)(4), 371(a)).

Subpart A—General Provisions

§ 123.1 Current good manufacturing practice.

The criteria in Part 110 of this chapter shall apply in determining whether the facilities, methods, practices, and controls for the manufacture, processing, packing, or holding of fish and seafood products are in conformance with and are operated or administered in conformity with good manufacturing practice to produce, under sanitary conditions, food for human consumption. The criteria in §§ 123.20, 123.35, 123.37, 123.40, and 123.80 set forth requirements in addition to those in Part 110 of this chapter for the breaded shrimp industry.

§ 123.3 Definitions.

For the purposes of this part, the following definitions apply:

(a) "Breaded shrimp" means any form of frozen raw breaded shrimp or frozen raw lightly breaded shrimp which complies with or is in semblance of that defined in §§ 161.175 and 161.176, respectively, of this chapter.

(b) "Peeling" shall include the operation whereby raw shrimp are prepared to comply with § 161.175(c) of this chapter and, where applicable, the alimentary canal or vein is removed.

Subpart B—Buildings and Facilities

§ 123.20 Plants and grounds.

(a) Unloading platforms shall be:

(1) Made of a readily cleanable material.

(2) Equipped with drainage facilities adequate to accommodate all seepage and wash water.

(b) The product shall be so processed as to prevent contamination by exposure to areas involved in earlier processing steps, refuse, or other objectionable areas.

§ 123.35 Sanitary facilities and controls.

(a) Adequate hand-washing and sanitizing facilities shall be located in the processing area, easily accessible from the peeling and subsequent processing operations.

(b) Readily understandable signs directing employees handling shrimp to wash and sanitize their hands after each absence from post of duty shall be conspicuously posted in the peeling and subsequent processing areas and elsewhere in the plant as conditions require.

(c) Offal, debris, or refuse from any source whatsoever shall not be allowed to accumulate. Offal shall be placed in suitable, covered containers and shall be removed not less than once daily or shall be continuously removed by flumes, conveyors, or chutes.

§ 123.37 Sanitary operations.

(a) Batter application equipment, except that prescribed under § 123.80(d)(3), shall be flushed and sanitized at least every 4 hours during plant operations. All batter application equipment shall be cleaned and sanitized at the end of the day's operation.

(b) Breading application equipment and utensils, excluding holding tanks and pneumatic systems, shall be thoroughly cleaned and sanitized at the end of the day's operation.

(c) All utensils used in processing and product-contact surfaces of equipment shall be thoroughly cleaned and sanitized at least every 4 hours during operation; however, this shall not apply to equipment for which other specific minimum cleaning times are established or to freezing equipment.

(d) Before beginning the day's operation, all utensils and product-contact surfaces of equipment, except for those prescribed under paragraph (b) of this section, shall be rinsed and sanitized.

(e) Containers used to convey or store food shall not be handled in a manner conducive to direct or indirect contamination of the contents.

Subpart C—Equipment

§ 123.40 Equipment and procedures.

(a) All food-contact surfaces (tanks, belts, tables, flumes, utensils, and other equipment) shall be of metal or other readily cleanable materials.

(b) All seams shall be smoothly soldered, welded, or bonded to prevent accumulation of shrimp, shrimp material, and debris.

(c) Each freezer and cold storage compartment used for raw materials, materials in process, or finished products shall be fitted with at least the following:

(1) An automatic control for regulating temperature, or an automatic alarm

system to indicate a significant temperature change in a manual operation.

(2) An indicating thermometer so installed as to show accurately the temperature within the compartment.

(3) A recording thermometer so installed as to indicate accurately at all times the temperature within the compartment.

(d) Thermometers or other temperature measuring devices shall have an accuracy of ±2° F.

Subpart D—[Reserved]

Subpart E—Production and Process Controls

§ 123.80 Processes and controls.

(a) *Raw materials.* (1) Fresh shrimp shall be adequately washed, inspected, and culled to remove shrimp that are filthy, putrid, or decomposed, and to remove all nonshrimp material.

(2) Every lot of shrimp that has been partially processed in another plant, including frozen shrimp, shall be inspected, and only cleaned, wholesome shrimp shall be processed.

(3) Fresh or partially processed shrimp shall be iced or otherwise refrigerated to maintain the shrimp at a temperature of 40° F or below until they are to be processed.

(4) Frozen shrimp shall be stored at a temperature of 0° F or below.

(5) Ingredients capable of supporting rapid bacterial growth shall be examined to assure that only clean, wholesome materials are used in production.

(b) *Defrosting of frozen shrimp.* (1) Defrosting shall be carried out in a sanitary manner and by such methods that the wholesomeness of the shrimp is not adversely affected; for example, in air at 45° F or below until other than hard frozen or in a continuous waterflow thaw tank or spray system.

(2) When a thaw tank is used, shrimp should not remain in the tank any longer than one-half hour after they are thawed.

(3) Shrimp entering the thaw tank should be free of exterior packaging material and substantially free of liner material.

(4) On removal from the thaw tank, shrimp shall be washed with a vigorous water spray.

(c) *Peeling operation.* (1) Shrimp shall be peeled into flumes that immediately transport the meat portion from the machines or peeling tables, except that shrimp may be peeled into seamless containers if the peeled meats are not held in such containers for more than 20 minutes before being flumed or conveyed from peeling tables. If shrimp are peeled into such containers, the containers shall be cleaned and sanitized as often as necessary to maintain them in a sanitary condition, but in no case less frequently than every 3 hours. Whenever a peeler is absent from his post of duty, the container used by such peeler shall be cleaned and sanitized before peeling is resumed.

(2) Sanitary drainage shall be provided to remove liquid waste from the peeling tables.

(3) Peeled shrimp being transported from one building of the plant to another shall be properly iced or refrigerated, covered, and protected.

(d) *Batter and breading operation.* (1) Shrimp shall be washed with a low-velocity spray or in unrecirculated flowing water at 50° F or below just prior to the initial batter or breading application, whichever comes first, except in those instances where a predust application is included in the process.

(2) In removing the batter or breading mixes or other dry ingredients from multiwalled bags:

(i) The outer layer of the bag shall first be removed.

(ii) The bag shall be slit in the exposed area and the contents removed without contact with the seam ends or closures.

(iii) If the entire contents are not removed at one time, the remainder shall be protected against contamination.

(3) Batter in enclosed equipment that assures a batter temperature of not more than 40° F shall be disposed of at the end of each work day, but under no circumstances less often than every 12 hours.

(4) Batter, except for that prescribed under paragraph (d)(3) of this section, shall be maintained at a temperature of 50° F or below and shall be disposed of at least every 4 hours during operations and at the end of the day's operation.

(5) Breading may be reused during a day's operation if it is sifted through a screen of one-quarter inch or smaller mesh. Breading remaining in the breading application equipment at the end of the day's operation may be reused within 20 hours if it is sifted as set forth above and placed in freezer storage in a covered sanitary container. All material removed by sifting shall be discarded.

(e) *Packing.* (1) Manual manipulation of breaded shrimp shall be kept to a minimum.

(2) The outer layers of the finished product package and the master carton shall bear a caution to keep the product thoroughly frozen and not to refreeze.

(3) Permanently legible code marks shall be placed on every finished package and master carton. Such marks should identify at least the date of packing and the plant where packed.

(4) The aggregate processing time, excluding the time required for thawing frozen raw material, shall be less than 2 hours. Processing time does not include time in iced or refrigerated storage.

(5) Breaded shrimp shall be placed into the freezer within 30 minutes after it is packaged.

(f) *Freezing and cold storage.* (1) The freezing method used shall reduce the temperature of the food product in all size packages to 32° F within 12 hours and shall produce a thoroughly frozen product within 24 hours.

(2) After freezing, the food shall be stored in such a manner that its temperature does not exceed 0° F and shall be handled in such manner as will maintain the thoroughly frozen condition.

(g) *Testing.* The microbiological condition of the operation shall be evaluated by the periodic collection and analysis of in-line and finished product samples coupled with sample-related inspections. This evaluation should be made at least weekly; more often when problems are encountered.

PART 129—PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER

Subpart A—General Provisions

Sec.
129.1 Current good manufacturing practice.
129.3 Definitions.

Subpart B—Buildings and Facilities

129.20 Plant construction and design.
129.35 Sanitary facilities.
129.37 Sanitary operations.

Subpart C—Equipment

129.40 Equipment and procedures.

Subpart D—[Reserved]

Subpart E—Production and Process Controls

129.80 Processes and controls.

AUTHORITY: Secs. 402(a)(4), 409, 701(a), 52 Stat. 1046, 1055; 72 Stat. 1785–1788 (21 U.S.C. 342(a)(4), 348, 371(a)).

Subpart A—General Provisions

§ 129.1 Current good manufacturing practice.

The applicable criteria in Part 110 of this chapter, as well as the criteria in §§ 129.20, 129.35, 129.37, 129.40, and 129.80 shall apply in determining whether the facilities, methods, practices, and controls used in the processing, bottling, holding, and shipping of bottled drinking water are in conformance with or are operated or administered in conformity with good manufacturing practice to assure that bottled drinking water is safe and that it has been processed, bottled, held, and transported under sanitary conditions.

§ 129.3 Definitions.

For the purposes of this part, the following definitions apply:

(a) "Approved source" when used in reference to a plant's product water or operations water means that the source of the water and the water therefrom, whether it be from a spring, artesian well, drilled well, municipal water supply, or any other source, shall have been inspected and the water sampled, analyzed, and found to be of a safe and sanitary quality in accordance with the applicable laws and regulations of the government agency or agencies having jurisdiction. The presence, in the plant, of current certificates or notifications of approval from the government agency or agencies having jurisdiction shall constitute approval of the source and the water supply.

(b) "Bottled drinking water" means all water which is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

(c) "Lot" means a collection of primary containers or unit packages of the same size, type, and style produced under conditions as nearly uniform as possible and designated by a common container code or marking.

(d) "Multiservice containers" means containers intended for use more than one time.

(e) "Nontoxic materials" means materials for product water contact surfaces utilized in the transporting, processing, storing, and packaging of bottled drinking water, which are free of substances which may render the water injurious to health or which may adversely affect the flavor, color, odor, or bacteriological quality of the water.

(f) "Operations water" means water which is delivered under pressure to a plant for container washing, hand washing, plant and equipment cleanup and for other sanitary purposes.

(g) "Primary container" means the immediate container in which the product water is packaged.

(h) "Product water" means processed water used by a plant for bottled drinking water.

(i) "Shall and should." "Shall" refers to mandatory requirements and "should" refers to recommended or advisory procedures or equipment.

(j) "Shipping case" means a container in which one or more primary containers of the product are held.

(k) "Single-service container" means a container intended for one time usage only.

(l) "Unit package" means a standard commercial package of bottled drinking water, which may consist of one or more containers.

Subpart B—Buildings and Facilities

§ 129.20 Plant construction and design.

(a) The bottling room shall be separated from other plant operations or storage areas by tight walls, ceilings, and self-closing doors to protect against contamination. Conveyor openings shall not exceed the size required to permit passage of containers.

(b) If processing operations are conducted in other than a sealed system under pressure, adequate protection shall be provided to preclude contamination of the water and the system.

(c) Adequate ventilation shall be provided to minimize condensation in processing rooms, bottling rooms, and in container washing and sanitizing areas.

(d) The washing and sanitizing of containers for bottled drinking water shall be performed in an enclosed room. The washing and sanitizing operation shall be positioned within the room so as to minimize any possible post-sanitizing contamination of the containers before they enter the bottling room.

(e) Rooms in which product water is handled, processed, or held or in which containers, utensils, or equipment are washed or held shall not open directly into any room used for domestic household purposes.

§ 129.35 Sanitary facilities.

Each plant shall provide adequate sanitary facilities including, but not limited to, the following:

(a) *Product water and operations water*—(1) *Product water.* The product water supply for each plant shall be from an approved source properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality which shall be in conformance at all times with the applicable laws and regulations of the government agency or agencies having jurisdiction.

(2) *Operations water.* If different from the product water supply, the operations water supply shall be obtained from an approved source properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality which shall be in conformance at all times with the applicable laws and regulations of the government agency or agencies having jurisdiction.

(3) *Product water and operations water from approved sources.* (i) Water samples shall be taken from approved sources by the plant as often as is necessary, but at a minimum frequency of twice each year with an interval between samples of not less than 5 months nor more than 7 months to assure that the supply is in conformance with the applicable standards, laws, and regulations of the government agency or agencies having jurisdiction. The sampling and analysis shall be by qualified plant personnel and shall be in addition to any sampling performed by the government agency or agencies having jurisdiction. Records of both government agency approval of the water source and the sampling and analysis performed by the plant shall be maintained on file at the plant.

(ii) Test and sample methods shall be those recognized and approved by the government agency or agencies having jurisdiction over the approval of the water source, and shall be consistent with the minimum requirements set forth in § 103.35 of this chapter.

(iii) Analysis of the samples may be performed for the plant by competent commercial laboratories.

(b) *Air under pressure.* Whenever air under pressure is directed at product water or a product water-contact surface, it shall be free of oil, dust, rust, excessive moisture, and extraneous materials; shall not affect the bacteriological quality of the water; and should not adversely affect the flavor, color, or odor of the water.

(c) *Locker and lunchrooms.* When employee locker and lunchrooms are provided, they shall be separate from plant operations and storage areas and shall be equipped with self-closing doors. The rooms shall be maintained in a clean and sanitary condition and refuse containers should be provided. Packaging or wrapping material or other processing supplies shall not be stored in locker or lunchrooms.

NOTE: Paragraph (a)(3) of § 129.35 (formerly § 128d.5) was partially stayed at 40 FR 51194, Nov. 4, 1975.

§ 129.37 Sanitary operations.

(a) The product water-contact surfaces of all multiservice containers, utensils, pipes, and equipment used in the transportation, processing, handling, and storage of product water shall be clean and adequately sanitized. All product water-contact surfaces shall be inspected by plant personnel as often as necessary to maintain the sanitary condition of such surfaces and to assure they are kept free of scale, evidence of oxidation, and other residue. The presence of any unsanitary condition, scale, residue, or oxidation shall be immediately remedied by adequate cleaning and sanitizing of that product water-contact surface prior to use.

(b) After cleaning, all multiservice containers, utensils, and disassembled piping and equipment shall be transported and stored in such a manner as to assure drainage and shall be protected from contamination.

(c) Single-service containers and caps or seals shall be purchased and stored in sanitary closures and kept clean therein in a clean, dry place until used. Prior to use they shall be examined, and as necessary, washed, rinsed, and sanitized and shall be handled in a sanitary manner.

(d) Filling, capping, closing, sealing, and packaging of containers shall be done in a sanitary manner so as to preclude contamination of the bottled drinking water.

Subpart C—Equipment

§ 129.40 Equipment and procedures.

(a) *Suitability.* (1) All plant equipment and utensils shall be suitable for their intended use. This includes all collection and storage tanks, piping, fittings, connections, bottle washers, fillers, cappers, and other equipment which may be used to store, handle, process, package, or transport product water.

(2) All product water contact surfaces shall be constructed of nontoxic and nonabsorbant material which can be adequately cleaned and sanitized and is in compliance with section 409 of the act.

(b) *Design.* Storage tanks shall be of the type that can be closed to exclude all foreign matter and shall be adequately vented.

Subpart D—[Reserved]

Subpart E—Production and Process Controls

§ 129.80 Processes and controls.

(a) *Treatment of product water.* All treatment of product water by distillation, ion-exchanging, filtration, ultraviolet treatment, reverse osmosis, carbonation, mineral addition, or any other process shall be done in a manner so as to be effective in accomplishing its intended purpose and in accordance with section 409 of the Federal Food, Drug, and Cosmetic Act. All such processes shall be performed in and by equipment and with substances which will not adulterate the bottled product. A record of the type and date of physical inspections of such equipment, conditions found, and the performance and effectiveness of such equipment shall be maintained by the plant. Product water samples shall be taken after processing and prior to bottling by the plant and ana-

lyzed as often as is necessary to assure uniformity and effectiveness of the processes performed by the plant. The methods of analysis shall be those approved by the government agency or agencies having jurisdiction.

(b) *Containers.* (1) Multiservice primary containers shall be adequately cleaned, sanitized, and inspected just prior to being filled, capped, and sealed. Containers found to be unsanitary or defective by the inspection shall be reprocessed or discarded. All multiservice primary containers shall be washed, rinsed, and sanitized by mechanical washers or by any other method giving adequate sanitary results. Mechanical washers shall be inspected as often as is necessary to assure adequate performance. Records of physical maintenance, inspections and conditions found, and performance of the mechanical washer shall be maintained by the plant.

(2) Multiservice shipping cases shall be maintained in such condition as to assure they will not contaminate the primary container or the product water. Adequate dry or wet cleaning procedures shall be performed as often as necessary to maintain the cases in satisfactory condition.

(c) *Cleaning and sanitizing solutions.* Cleaning and sanitizing solutions utilized by the plant shall be sampled and tested by the plant as often as is necessary to assure adequate performance in the cleaning and sanitizing operations. Records of these tests shall be maintained by the plant. .

(d) *Sanitizing operations.* Sanitizing operations, including those performed by chemical means or by any other means such as circulation of live steam or hot water, shall be adequate to effect sanitization of the intended product water-contact surfaces and any other critical area. The plant should maintain a record of the intensity of the sanitizing agent and the time duration that the agent was in contact with the surface being sanitized. The following times and intensities shall be considered a minimum:

(1) Steam in enclosed system: At least 170° F for at least 15 minutes or at least 200° F for at least 5 minutes.

(2) Hot water in enclosed system: At least 170° F for at least 15 minutes or at least 200° F for at least 5 minutes.

(3) Chemical sanitizers shall be equivalent in bactericidal action to a 2-minute exposure of 50 parts per million of available chlorine at 57° F when used as an immersion or circulating solution. Chemical sanitizers applied as a spray or fog shall have as a minimum 100 parts per million of available chlorine at 57° F or its equivalent in bactericidal action.

(4) 0.1 part per million ozone water solution in an enclosed system for at least 5 minutes.

(5) When containers are sanitized using a substance other than one provided for in § 178.1010 of this chapter, such substance shall be removed from the surface of the container by a rinsing procedure. The final rinse, prior to filling the container with product water, shall be performed with a disinfected water rinse free of pathogenic bacteria or by an additional sanitizing procedure equivalent in bactericidal action to that required in paragraph (d)(3) of this section.

(e) *Unit package production code.* Each unit package from a batch or segment of a continuous production run of bottled drinking water shall be identified by a production code. The production code shall identify a particular batch or segment of a continuous production run and the day produced. The plant shall record and maintain information as to the kind of product, volume produced, date produced, lot code used, and the distribution of the finished product to wholesale and retail outlets.

(f) *Filling, capping, or sealing.* During the process of filling, capping or sealing either single-service or multiservice containers, the performance of the filler, capper or sealer shall be monitored and the filled containers visually or electronically inspected to assure they are sound, properly capped or sealed, and coded and labeled. Containers which are not satisfactory shall be reprocessed or rejected. Only nontoxic containers and closures shall be used. All containers and closures shall be sampled and inspected to ascertain that they are free from contamination. At least once each 3 months, a bacteriological swab and/or rinse count should be made from at least four containers and closures selected just prior to filling and sealing. No more than one of the four samples may exceed more than one bacteria per milliliter of capacity or one colony per square centimeter of surface area. All samples shall be free of coliform organisms. The procedure and apparatus for these bacteriological tests shall be in conformance with those recognized by the government agency or agencies having jurisdiction. Tests shall be performed either by qualified plant personnel or a competent commercial laboratory.

(g) *Compliance procedures.* To assure that the plant's production of bottled drinking water is in compliance with the applicable standards, laws, and regulations of the government agency or agencies having jurisdiction, the plant shall:

(1) For bacteriological purposes, take and analyze at least once a week a representative sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production. The representative sample shall consist of primary containers of product or unit packages of product.

(2) For chemical, physical, and radiological purposes, take and analyze at least semi-annually a representative sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production. The representative sample shall consist of primary containers of product or unit packages of product.

(3) Analyze such samples by methods approved by the government agency or agencies having jurisdiction. The plant shall maintain records of date of sampling, type of product sampled, production code, and results of the analysis.

(h) *Record retention.* All records required by §§ 129.1, 129.20, 129.35, 129.37, 129.40, and 129.80 shall be maintained at the plant for not less than 2 years. Plants shall also retain, on file at the plant, current certificates or notifications of approval issued by the government agency or agencies approving the plant's source and supply of product water and operations water. All required documents shall be available for official review at reasonable times.

PART 130—FOOD STANDARDS: GENERAL

Subpart A—General Provisions

Sec.
130.3 Definitions and interpretations.
130.5 Procedure for establishing a food standard.
130.6 Review of Codex Alimentarius food standards.
130.8 Conformity to definitions and standards of identity.
130.12 General methods for water capacity and fill of containers.
130.14 General statements of substandard quality and substandard fill of container.
130.17 Temporary permits for interstate shipment of experimental packs of food varying from the requirements of definitions and standards of identity.

Subpart B—Food Additives in Standardized Foods

130.20 Food additives proposed for use in foods for which definitions and standards of identity are established.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046 as amended, 1055–1056 as amended (21 U.S.C. 341, 371).

Subpart A—General Provisions

§ 130.3 Definitions and interpretations.

(a) The definitions and interpretations of terms contained in section 201 of the act shall be applicable also to such terms when used in regulations promulgated under the act.

(b) If a regulation prescribing a definition and standard of identity for a food has been promulgated under section 401 of the act and the name therein specified for the food is used in any other regulation under section 401 or any other provision of the act, such name means the food which conforms to such definition and standard, except as otherwise specifically provided in such other regulation.

(c) No provision of any regulation prescribing a definition and standard of identity or standard of quality or fill of container under section 401 of the act shall be construed as in any way affecting the concurrent applicability of the general provisions of the act and the regulations thereunder relating to adulteration and misbranding. For example, all regulations under section 401 contemplate that the food and all articles used as components or ingredients thereof shall not be poisonous or deleterious and shall be clean, sound, and

fit for food. A provision in such regulations for the use of coloring or flavoring does not authorize such use under circumstances or in a manner whereby damage or inferiority is concealed or whereby the food is made to appear better or of greater value than it is.

(d) "Safe and suitable" means that the ingredient:

(1) Performs an appropriate function in the food in which it is used.

(2) Is used at a level no higher than necessary to achieve its intended purpose in that food.

(3) Is not a food additive or color additive as defined in section 201 (s) or (t) of the Federal Food, Drug, and Cosmetic Act as used in that food, or is a food additive or color additive as so defined and is used in conformity with regulations established pursuant to section 409 or 706 of the act.

§ 130.5 Procedure for establishing a food standard.

(a) The procedure for establishing a food standard under section 401 of the act shall be governed by Part 2 of this chapter.

(b) Any petition for a food standard shall show that the proposal, if adopted, would promote honesty and fair dealing in the interest of consumers.

(c) Any petition for a food standard shall assert that the petitioner commits himself to substantiste the information in the petition by evidence in a public hearing, if such a hearing becomes necessary.

(d) If a petitioner fails to appear, or to substantiate the information in his petition, at a public hearing on the matter, the Commissioner may either (1) withdraw the regulation and terminate the proceeding or (2) if he concludes that it is in accordance with the requirements of section 401 of the act, continue the proceeding and introduce evidence to substantiate such information.

§ 130.6 Review of Codex Alimentarius food standards.

(a) All food standards adopted by the Codex Alimentarius Commission will be reviewed by the Food and Drug Administration and will be accepted without change, accepted with change, or not accepted.

(b) Review of Codex standards will be accomplished in one of the following three ways:

(1) Any interested person may petition the Commissioner to adopt a Codex standard, with or without change, by proposing a new standard or an appropriate amendment of an existing standard, pursuant to section 401 of the act. Any such petition shall specify any deviations from the Codex standard, and the reasons for any such deviations. The Commissioner shall publish such a petition in the FEDERAL REGISTER as a proposal, with an opportunity for comment, if reasonable grounds are provided in the petition. Any published proposal shall state any deviations from the Codex standard and the stated reasons therefor.

(2) The Commissioner may on his own initiative propose by publication in the FEDERAL REGISTER the adoption of a Codex standard, with or without change, through a new standard or an appropriate amendment to an existing standard, pursuant to section 401 of the act. Any such proposal shall specify any deviations from the Codex standard, and the reasons for any such deviations.

(3) Any Codex standard not handled under paragraph (b) (1) or (2) of this section may be published in the FEDERAL REGISTER for review and informal comment. Interested persons shall be requested to comment on the desirability and need for the standard, on the specific provisions of the standard, on additional or different provisions that should be included in the standard, and on any other pertinent points. After reviewing all such comments, the Commissioner either shall publish a proposal to establish a food standard pursuant to section 401 of the act covering the food involved, or shall publish a notice terminating consideration of such a standard.

(c) All interested persons are encouraged to confer with different interest groups (consumers, industry, the academic community, professional organizations, and others) in formulating petitions or comments pursuant to paragraph (b) of this section. All such petitions or comments are requested to include a statement of any meetings and discussions that have been held with other interest groups. Appropriate weight will be given by the Commissioner to petitions or comments that reflect a consensus of different interest groups.

§ 130.8 Conformity to definitions and standards of identity.

In the following conditions, among others, a food does not conform to the definition and standard of identity therefor:

(a) If it contains an ingredient for which no provision is made in such definition and standard, unless such ingredient is an incidental additive introduced at a nonfunctional and insignificant level as a result of its deliberate and purposeful addition to another ingredient permitted by the terms of the applicable standard and the presence of such incidental additive in unstandardized foods has been exempted from label declaration as provided in § 101.100 of this chapter.

(b) If it fails to contain any one or more ingredients required by such definition and standard;

(c) If the quantity of any ingredient or component fails to conform to the limitation, if any, prescribed therefor by such definition and standard.

§ 130.12 General methods for water capacity and fill of containers.

For the purposes of regulations promulgated under section 401 of the act:

(a) The term "general method for water capacity of containers" means the following method:

(1) In the case of a container with lid attached by double seam, cut out the lid without removing or altering the height of the double seam.

(2) Wash, dry, and weigh the empty container.

(3) Fill the container with distilled water at 68° F to 3/16 inch vertical distance below the top level of the container, and weigh the container thus filled.

(4) Subtract the weight found in paragraph (a) (2) of this section from the weight found in paragraph (a) (3) of this section. The difference shall be considered to be the weight of water required to fill the container.

In the case of a container with lid attached otherwise than by double seam, remove the lid and proceed as directed in paragraphs (a) (2) to (4) of this section, except that under paragraph (a) (3) of this section, fill the container to the level of the top thereof.

(b) The term "general method for fill of containers" means the following method:

(1) In the case of a container with lid attached by double seam, cut out the lid without removing or altering the height of the double seam.

(2) Measure the vertical distance from the top level of the container to the top level of the food.

(3) Remove the food from the container; wash, dry, and weigh the container.

(4) Fill the container with water to 3/16 inch vertical distance below the top level of the container. Record the temperature of the water, weigh the container thus filled, and determine the weight of the water by subtracting the weight of the container found in paragraph (b) (3) of this section.

(5) Maintaining the water at the temperature recorded in paragraph (b) (4) of this section, draw off water from the container as filled in paragraph (b) (4) of this section to the level of the food found in paragraph (b) (2) of this section, weigh the container with remaining water, and determine the weight of the remaining water by subtracting the weight of the container found in paragraph (b) (3) of this section.

(6) Divide the weight of water found in paragraph (b) (5) of this section by the weight of water found in paragraph (b) (4) of this section, and multiply by 100. The result shall be considered to be the percent of the total capacity of the container occupied by the food.

In the case of a container with lid attached otherwise than by double seam, remove the lid and proceed as directed in paragraphs (b) (2) to (6) of this section, except that under paragraph (b) (4) of this section, fill the container to the level of the top thereof.

§ 130.14 General statements of substandard quality and substandard fill of container.

For the purposes of regulations promulgated under section 401 of the act:

(a) The term "general statement of substandard quality" means the statement "Below Standard in Quality Good Food—Not High Grade" printed in two

lines of Cheltenham bold condensed caps. The words "Below Standard in Quality" constitute the first line, and the second immediately follows. If the quantity of the contents of the container is less than 1 pound, the type of the first line is 12-point, and of the second, 8-point. If such quantity is 1 pound or more, the type of the first line is 14-point, and of the second, 10-point. Such statement is enclosed within lines, not less than 6 points in width, forming a rectangle. Such statement, with enclosing lines, is on a strongly contrasting, uniform background, and is so placed as to be easily seen when the name of the food or any pictorial representation thereof is viewed, wherever such name or representation appears so conspicuously as to be easily seen under customary conditions of purchase.

(b) The term "general statement of substandard fill" means the statement "Below Standard in Fill" printed in Cheltenham bold condensed caps. If the quantity of the contents of the container is less than 1 pound, the statement is in 12-point type; if such quantity is 1 pound or more, the statement is in 14-point type. Such statement is enclosed within lines, not less than 6 points in width, forming a rectangle; but if the statement specified in paragraph (a) of this section is also used, both statements (one following the other) may be enclosed within the same rectangle. Such statement or statements, with enclosing lines, are on a strongly contrasting, uniform background, and are so placed as to be easily seen when the name of the food or any pictorial representation thereof is viewed, wherever such name or representation appears so conspicuously as to be easily seen under customary conditions of purchase.

§ 130.17 Temporary permits for interstate shipment of experimental packs of food varying from the requirements of definitions and standards of identity.

(a) The Food and Drug Administration recognizes that before petitions to amend food standards can be submitted, appropriate investigations of potential advances in food technology sometimes require tests in interstate markets of the advantages to and acceptance by consumers of experimental packs of food varying from applicable definitions and standards of identity prescribed under section 401 of the act.

(b) It is the purpose of the Food and Drug Administration to permit such tests when it can be ascertained that the sole purpose of the tests is to obtain data necessary for reasonable grounds in support of a petition to amend food standards, that the tests are necessary to the completion or conclusiveness of an otherwise adequate investigation, and that the interests of consumers are adequately safeguarded; permits for such tests shall normally be for a period not to exceed 15 months. The Commissioner, for good cause shown by the applicant, may provide for a longer test market period. The Food and Drug Administration will therefore refrain from recommending regulatory proceedings under the act on the charge that a food does not conform to an applicable standard, if the person who introduces or causes the introduction of the food into interstate commerce holds an effective permit from the Commissioner providing specifically for those variations in respect to which the food fails to conform to the applicable definition and standard of identity. The test period will begin on the date the person holding an effective permit from the Commissioner introduces or causes the introduction of the food covered by the permit into interstate commerce but not later than 3 months after notice of the issuance of the permit is published in the FEDERAL REGISTER. The Commissioner shall be notified in writing of the date on which the test period begins as soon as it is determined.

(c) Any person desiring a permit may file with the Commissioner a written application in triplicate containing as part thereof the following:

(1) Name and address of the applicant.

(2) A statement of whether or not the applicant is regularly engaged in producing the food involved.

(3) A reference to the applicable definition and standard of identity (citing applicable section of regulations).

(4) A full description of the proposed variation from the standard.

(5) The basis upon which the food so varying is believed to be wholesome and nondeleterious.

(6) The amount of any new ingredient to be added; the amount of any ingredient, required by the standard, to be eliminated; any change of concentration not contemplated by the standard; or any change in name that would more appropriately describe the new product under test. If such new ingredient is not a commonly known food ingredient, a description of its properties and basis for concluding that it is not a deleterious substance.

(7) The purpose of effecting the variation.

(8) A statement of how the variation is of potential advantage to consumers. The statement shall include the reasons why the applicant does not consider the data obtained in any prior investigations which may have been conducted sufficient to support a petition to amend the standard.

(9) The proposed label (or an accurate draft) to be used on the food to be market tested. The label shall conform in all respects to the general requirements of the act and shall provide a means whereby the consumer can distinguish between the food being tested and such food complying with the standard.

(10) The period during which the applicant desires to introduce such food into interstate commerce, with a statement of the reasons supporting the need for such period. If a period longer than 15 months is requested, a detailed explanation of why a 15-month period is inadequate shall be provided.

(11) The probable amount of such food that will be distributed. The amount distributed should be limited to the smallest number of units reasonably required for a bona fide market test. Justification for the amount requested shall be included.

(12) The areas of distribution.

(13) The address at which such food will be manufactured.

(14) A statement of whether or not such food has been or is to be distributed in the State in which it was manufactured.

(15) If it has not been or is not to be so distributed, a statement showing why.

(16) If it has been or is to be so distributed, a statement of why it is deemed necessary to distribute such food in other States.

(d) The Commissioner may require the applicant to furnish samples of the food varying from the standard and to furnish such additional information as may be deemed necessary for action on the application.

(e) If the Commissioner concludes that the variation may be advantageous to consumers and will not result in failure of the food to conform to any provision of the act except section 403(g), a permit shall be issued to the applicant for interstate shipment of such food. The terms and conditions of the permit shall be those set forth in the application with such modifications, restrictions, or qualifications as the Commissioner may deem necessary and state in the permit.

(f) The terms and conditions of the permit may be modified at the discretion of the Commissioner or upon application of the permittee during the effective period of the permit.

(g) The Commissioner may revoke a permit for cause, which shall include but not be limited to the following:

(1) That the permittee has introduced a food into interstate commerce contrary to the terms and conditions of the permit.

(2) That the application for a permit contains an untrue statement of a material fact.

(3) That the need therefor no longer exists.

(h) During the period within which any permit is effective, it shall be deemed to be included within the terms of any guaranty or undertaking otherwise effective pursuant to the provisions of section 303(c) of the act.

(i) If an application is made for an extension of the permit, it shall be accompanied by a description of experiments conducted under the permit, tentative conclusions reached, and reasons why further experimental shipments are considered necessary. The application for an extension shall be filed not later than 3 months prior to the expiration date of the permit and shall be accompanied by a petition to amend the affected food standard. If the Commissioner concludes that it will be in the interest of consumers to issue an extension of the time period for the market test, a notice will be published in the

FEDERAL REGISTER stating that fact. The notice will include an invitation to all interested persons to participate in the market test under the same conditions that applied to the initial permit holder, including labeling and the amount to be distributed, except that the designated area of distribution shall not apply. The extended market test period shall not begin prior to the publication of a notice in the FEDERAL REGISTER granting the extension and shall terminate either on the effective date of an affirmative order ruling on the proposal or 30 days after a negative order ruling on the proposal, whichever the case may be. Any interested person who accepts the invitation to participate in the extended market test shall notify the Commissioner in writing of that fact, the amount to be distributed, and the area of distribution; and along with such notification, he shall submit the labeling under which the food is to be distributed.

(j) Notice of the granting or revocation of any permit shall be published in the FEDERAL REGISTER.

(k) All applications for a temporary permit, applications for an extension of a temporary permit, and related records are available for public disclosure when the notice of a permit or extension thereof is published in the FEDERAL REGISTER. Such disclosure shall be in accordance with the rules established in Part 4 of this chapter.

(l) Any person who contests denial, modification, or revocation of a temporary permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Subpart F of Part 2 of this chapter.

Subpart B—Food Additives in Standardized Foods

§ 130.20 Food additives proposed for use in foods for which definitions and standards of identity are established.

(a) Where a petition is received for the issuance or amendment of a regulation establishing a definition and standard of identity for a food under section 401 of the act, which proposes the inclusion of a food additive in such definition and standard of identity, the provisions of the regulations in Part 171 of this chapter shall apply with respect to the information that must be submitted with respect to the food additive. Since section 409(b)(5) of the act requires that the Commissioner publish notice of a petition for the establishment of a food additive regulation within 30 days after filing, notice of a petition relating to a definition and standard of identity shall also be published within that time limitation if it includes a request, so designated, for the establishment of a regulation pertaining to a food additive.

(b) If a petition for a definition and standard of identity contains a proposal for a food additive regulation, and the petitioner fails to designate it as such, the Commissioner, upon determining that the petition includes a proposal for a food additive regulation, shall so notify the petitioner and shall thereafter proceed in accordance with the regulations in Part 171 of this chapter.

PART 131—MILK AND CREAM

Subpart A—General Provisions

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131.135 Lowfat milk.
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131.150 Heavy cream.
131.155 Light cream.
131.157 Light whipping cream.
131.160 Sour cream.
131.162 Acidified sour cream.
131.164 Sour cream dressing.
131.180 Half-and-half.
131.185 Sour half-and-half.
131.187 Acidified sour half-and-half.
131.189 Sour half-and-half dressing.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046 as amended, 1055–1056, as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 341, 371).

Subpart A—General Provisions

§ 131.3 Definitions.

(a) "Cream" means the liquid milk product high in fat separated from milk, which may have been adjusted by adding thereto: Milk, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Cream contains not less than 18 percent milkfat.

(b) "Pasteurized" when used to describe a dairy product means that every particle of such product shall have been heated in properly operated equipment to one of the temperatures specified in the table of this paragraph and held continuously at or above that temperature for the specified time (or other time/temperature relationship which has been demonstrated to be equivalent thereto in microbial destruction):

Temperature:	*Time*
145°F[1]	30 minutes
161°F[1]	15 seconds
191°F	1 second
204°F	0.05 second
212°F	0.01 second

[1] If the dairy ingredient has a fat content of 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 5°F.

(c) "Ultra-pasteurized" when used to describe a dairy product means that such product shall have been thermally processed at or above 280°F for at least 2 seconds, either before or after packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.

§ 131.25 Whipped cream products containing flavoring or sweetening.

The unqualified name "whipped cream" should not be applied to any product other than one made by whipping the cream that complies with the standards of identity for whipping cream (§§ 131.150 and 131.157 of this chapter). If flavoring and/or sweetening is added, the resulting product is a flavored and/or sweetened whipped cream, and should be so identified.

(Secs. 401, 403, 52 Stat. 1047, 1048; 21 U.S.C. 341, 343)

Subpart B—Requirements for Specific Standardized Milk and Cream

§ 131.110 Milk.

(a) *Description.* Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows. Milk that is in final package form for beverage use shall have been pasteurized or ultra-pasteurized, and shall contain not less than 8¼ percent milk solids not fat and not less than 3¼ percent milkfat. Milk may have been adjusted by separating part of the milkfat therefrom, or by adding thereto cream, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Milk may be homogenized.

(b) *Vitamin addition* (Optional). (1) If added, vitamin A shall be present in such quantity that each quart of the food contains not less than 2000 International Units thereof within limits of good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each quart of the food contains 400 International Units thereof within limits of good manufacturing practice.

(c) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Carriers for vitamins A and D.

(2) Characterizing flavoring ingredients (with or without coloring, nutritive sweetener, emulsifiers, and stabilizers) as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Natural and artificial food flavorings.

(d) *Methods of analysis.* Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.[2]

(1) Milk fat content—"Fat, Roese-Gottlieb Method—Official Final Action," section 16.052.[2]

(2) Milk solids not fat content—Calculated by subtracting the milk fat content from the total solids content as determined by the method "Total Solids, Method I—Official Final Action," section 16.032.[2]

(3) Vitamin D content—"Vitamin D—Official Final Action," sections 39.149–39.162.[2]

(e) *Nomenclature.* The name of the food is "milk". The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

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[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name:

(i) If vitamins are added, the phrase "vitamin A" or "vitamin A added", or "vitamin D" or "vitamin D added", or "vitamin A and D" or "vitamins A and D added", as is appropriate. The word "vitamin" may be abbreviated "vit.".

(ii) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(2) The following terms may appear on the label:

(i) The word "pasteurized" if the food has been pasteurized.

(ii) The word "homogenized" if the food has been homogenized.

(f) *Label declaration.* When used in the food, each of the ingredients specified in paragraphs (b) and (c) (2) of this section shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 131.115 Concentrated milk.

(a) *Description.* Concentrated milk is the liquid food obtained by partial removal of water from milk. The milkfat and total milk solids contents of the food are not less than 7.5 and 25.5 percent, respectively. It is pasteurized, but is not processed by heat so as to prevent spoilage. It may be homogenized.

(b) *Vitamin addition* (Optional). If added, vitamin D shall be present in such quantity that each fluid ounce of the food contains 25 International Units thereof, within limits of good manufacturing practice.

(c) *Optional ingredients.* The following safe and suitable optional ingredients may be used:

(1) Carriers for vitamins A and D.

(2) Characterizing flavoring ingredients, with or without coloring, as follows:

(i) Fruit and fruit juice, including concentrated fruit and fruit juice.

(ii) Natural and artificial food flavoring.

(d) *Methods of analysis.* Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.[2]

(1) Milkfat content—"Fat—Official Final Action," section 16.129.[2]

(2) Total milk solids—"Total Solids—Official Final Action," section 16.127.[2]

(3) Vitamin D content—"Vitamin D in Milk—Official Final Action," sections 39–149–39.162.[2]

(e) *Nomenclature.* The name of the food is "Concentrated milk" or alternatively "Condensed milk." If the food contains added vitamin D, the phrase "vitamin D" or "vitamin D added" shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name. The word "homogenized" may appear on the label if the food has been homogenized. The name of the food shall include a declaration of the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(f) *Label declaration.* When used in the food, the optional ingredients specified in paragraph (b) of this section shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 131.120 Sweetened condensed milk.

(a) *Description.* Sweetened condensed milk is the food obtained by the partial removal of water only from a mixture of milk and safe and suitable nutritive sweetener. The finished food contains not less than 8.5 percent by weight of milkfat, and not less than 28 percent by weight of total milk solids. The quantity of nutritive sweetener used is sufficient to prevent spoilage. The food is pasteurized, and may be homogenized.

(b) *Optional ingredients.* Safe and suitable characterizing flavoring ingredients, with or without coloring, as follows:

(1) Fruit and fruit juice, including concentrated fruit and fruit juice.

(2) Natural and artificial food flavoring.

(c) *Method of analysis.* The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970, section 16.142, under "Fat—Official Final Action."[2]

(d) *Nomenclature.* The name of the food is "Sweetened condensed milk". The word "homogenized" may appear on the label if the food has been homogenized. The name of the food shall include a declaration of the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(e) *Label declaration.* The optional sweetener used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 131.125 Nonfat dry milk.

(a) *Description.* Nonfat dry milk is the product obtained by removal of water only from pasteurized skim milk. It contains not more than 5 percent by weight of moisture, and not more than 1½ percent by weight of milkfat unless otherwise indicated.

(b) *Optional ingredients.* Safe and suitable characterizing flavoring ingredients, with or without coloring, as follows:

(1) Fruit and fruit juice, including concentrated fruit and fruit juice.

(2) Natural and artificial food flavoring.

(c) *Methods of analysis.* Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.[2]

(1) Moisture content—"Moisture—Official Final Action," section 16.149.[2]

(2) Milkfat content—"Fat in Dried Milk—Official Final Action," sections 16.156–16.157.[2]

(d) *Nomenclature.* The name of the food is "Nonfat dry milk". If the fat content is over 1½ percent by weight, the name of the food on the principal display panel or panels shall be accompanied by the statement "Contains ____% milkfat", the blank to be filled in with the percentage to the nearest one-tenth of 1 percent of fat contained, within limits of good manufacturing practice. The name of the food shall include a declaration of the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

§ 131.127 Nonfat dry milk fortified with vitamins A and D.

(a) *Description.* Nonfat dry milk fortified with vitamins A and D conforms to the standard of identity for nonfat dry milk, except that vitamins A and D are added as prescribed by paragraph (b) of this section.

(b) *Vitamin addition.* (1) Vitamin A is added in such quantity that, when prepared according to label directions, each quart of the reconstituted product contains 2000 International Units thereof.

(2) Vitamin D is added in such quantity that, when prepared according to label directions, each quart of the reconstituted product contains 400 International Units thereof.

(3) The requirements of this paragraph will be deemed to have been met if reasonable overages, within limits of good manufacturing practice, are present to ensure that the required levels of vitamins are maintained throughout the expected shelf life of the food under customary conditions of distribution.

(c) *Optional ingredients.* The following safe and suitable optional ingredients may be used:

(1) Carriers for vitamins A and D.

(2) Characterizing flavoring ingredients, with or without coloring, as follows:

(i) Fruit and fruit juice, including concentrated fruit and fruit juice.

(ii) Natural and artificial food flavoring.

(d) *Methods of analysis.* Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.[2]

(1) Moisture content—"Moisture—Official Final Action," section 16.149.[2]

(2) Milkfat content—"Fat in Dried Milk—Official Final Action," sections 16.156–16.157.[2]

(e) *Nomenclature.* The name of the food is "Nonfat dry milk fortified with vitamins A and D". If the fat content is over 1½ percent by weight, the name of the food on the principal display panel or panels shall be accompanied by the statement "Contains __% milkfat", the blank to be filled in to the nearest one-tenth of 1 percent with the percentage of fat contained within limits of good manufacturing practice. The name of the food shall be include a declaration of the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

§ 131.130 Evaporated milk.

(a) *Description.* Evaporated milk is the liquid food obtained by the partial removal of water from milk. The milkfat and total milk solids contents of the food are not less than 7.5 and 25.5 percent, respectively. Evaporated milk contains added vitamin D as prescribed by para-

[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

graph (b) of this section. It is homogenized. It is sealed in a container and so processed by heat, either before or after sealing, as to prevent spoilage.

(b) *Vitamin addition.* (1) Vitamin D shall be present in such quantity that each fluid ounce of the food contains 25 International Units thereof within limits of good manufacturing practice.

(2) Addition of vitamin A is optional. If added, vitamin A shall be present in such quantity that each fluid ounce of the food contains not less than 125 International Units thereof within limits of good manufacturing practice.

(c) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Carriers for vitamins A and D.

(2) Emulsifiers.

(3) Stabilizers, with or without dioctyl sodium sulfosuccinate (when permitted by, and complying with the provisions of, § 172.810 of this chapter) as a solubilizing agent.

(4) Characterizing flavoring ingredients, with or without coloring, as follows:

(i) Fruit and fruit juice, including concentrated fruit and fruit juice.

(ii) Natural and artificial food flavoring.

(d) *Methods of analysis.* Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.[2]

(1) Milkfat content — "Fat—Official Final Action," section 16.129.[2]

(2) Total milk solids—"Total Solids—Official Final Action," section 16.127.[2]

(3) Vitamin D content—"Vitamin D in Milk—Official Final Action," sections 39.149–39.162.[2]

(e) *Nomenclature.* The name of the food is "Evaporated milk". The phrase "vitamin D" or "vitamin D added," or "vitamin A and D" or "vitamins A and D added", as is appropriate, shall immediately precede or follow the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name. The name of the food shall include a declaration of the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(f) *Label declaration.* When used in the food, each of the ingredients specified in paragraphs (b) (2) and (c) (2) and (3) of this section shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 131.135 Lowfat milk.

(a) *Description.* Lowfat milk is milk from which sufficient milkfat has been removed to produce a food having, within limits of good manufacturing practice, one of the following milkfat contents: ½, 1, 1½, or 2 percent. Lowfat milk is pasteurized or ultra-pasteurized, contains added vitamin A as prescribed by paragraph (b) of this section, and contains not less than 8¼ percent milk solids not fat. Lowfat milk may be homogenized.

(b) *Vitamin addition.* (1) Vitamin A shall be present in such quantity that each quart of the food contains not less than 2000 International Units thereof within limits of good manufacturing practice.

(2) Addition of vitamin D is optional. If added, vitamin D shall be present in such quantity that each quart of the food contains 400 International Units thereof within limits of good manufacturing practice.

(c) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Carriers for vitamins A and D.

(2) Concentrated skim milk, nonfat dry milk, or other milk derived ingredients to increase the nonfat solids content of the food: *Provided,* That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients.

(3) When one or more of the optional milk derived ingredients in paragraph (c) (2) of this section are used, emulsifiers, stabilizers, or both, in an amount not more than 2 percent by weight of the solids in such ingredients.

(4) Characterizing flavoring ingredients (with or without coloring, nutritive sweetener, emulsifiers, and stabilizers) as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Natural and artificial food flavorings.

(d) *Methods of analysis.* Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.[2]

(1) Milkfat content—"Fat, Roese-Gottlieb Method—Official Final Action," section 16.052.[2]

(2) Milk solids not fat content (or total nonfat solids content)—Calculated by subtracting the milkfat content from the total solids content as determined by the method "Total Solids, Method I—Official Final Action," section 16.032.[2]

(3) Vitamin D content—"Vitamin D—Official Final Action," sections 39.149–39.162.[2]

(e) *Nomenclature.* The name of the food is "Lowfat milk". The name of the food shall appear on the label in type of uniform size, style, and color. The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(i) The phrase "____% milkfat", the blank to be filled in with the fraction ½, or multiple thereof, to indicate the actual fat content of the food.

(ii) The phrase "vitamin A" or "vitamin A added", or, if vitamin D is added, the phrase "vitamins A and D added". The word "vitamin" may be abbreviated "vit.".

(iii) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(iv) The phrase "protein fortified" or "fortified with protein" if the food contains not less than 10 percent milk derived nonfat solids.

(2) The following terms may appear on the label:

(i) The word "pasteurized" if the food has been pasteurized.

(ii) The word "homogenized" if the food has been homogenized.

(f) *Label declaration.* When ingredients are used in the food as specified in paragraphs (b) (2) and (c) (2), (3), and (4) of this section, such ingredients shall be declared on the label as required by the applicable sections of Part 101 of this chapter except that concentrated skim milk and nonfat dry milk may be declared as "nonfat milk solids".

§ 131.145 Skim milk.

(a) *Description.* Skim milk is milk from which sufficient milkfat has been removed to reduce its milkfat content to less than 0.5 percent. Skim milk that is in final package form for beverage use shall have been pasteurized or ultra-pasteurized, shall contain added vitamin A as prescribed by paragraph (b) of this section, and shall contain not less than 8¼ percent milk solids not fat. Skim milk may be homogenized.

(b) *Vitamin addition.* (1) Vitamin A shall be present in such quantity that each quart of the food contains not less than 2000 International Units thereof within limits of good manufacturing practice.

(2) Addition of vitamin D is optional. If added, vitamin D shall be present in such quantity that each quart of the food contains 400 International Units thereof within limits of good manufacturing practice.

(c) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Carriers for vitamins A and D.

(2) Concentrated skim milk, nonfat dry milk, or other milk derived ingredients to increase the nonfat solids content of the food: *Provided,* That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients.

(3) When one or more of the optional milk derived ingredients in paragraph (c) (2) of this section are used, emulsifiers, stabilizers, or a combination of both, in an amount not more than 2 percent by weight of the solids in such ingredients.

(4) Characterizing flavoring ingredients (with or without coloring, nutritive sweetener, emulsifiers, and stabilizers) as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Natural and artificial food flavoring.

(d) *Methods of analysis.* Referenced methods are from "Official Methods of

[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.[2]

(1) Milkfat content—"Fat, Roese-Gottlieb Method—Official Final Action," section 16.052.[2]

(2) Milk solids not fat content (or total nonfat solids content)—Calculated by subtracting the milkfat content from the total solids content as determined by the method "Total Solids, Method I—Official Final Action," section 16.032.[2]

(3) Vitamin D content—"Vitamin D—Official Final Action," sections 39.149–39.162.[2]

(e) *Nomenclature.* The name of the food is "Skim milk" or alternatively "Nonfat milk". The name of the food shall appear on the label in type of uniform size, style, and color. The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(i) The phrase "vitamin A" or "vitamin A added", or, if vitamin D is added, the phrase "vitamins A and D" or "vitamins A and D added". The word "vitamin" may be abbreviated "vit.".

(ii) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(iii) The phrase "protein fortified" or "fortified with protein" if the food contains not less than 10 percent milk derived nonfat solids.

(2) The following terms may appear on the label:

(i) The word "pasteurized" if the food has been pasteurized.

(ii) The word "homogenized" if the food has been homogenized.

(f) *Label declaration.* When used in the food, each of the ingredients specified in paragraphs (b)(2) and (c)(2), (3), and (4) of this section shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 131.150 Heavy cream.

(a) *Description.* Heavy cream is cream which contains not less than 36 percent milkfat. It is pasteurized or ultra-pasteurized, and may be homogenized.

(b) *Optional ingredients.* The following safe and suitable optional ingredients may be used:

(1) Emulsifiers.

(2) Stabilizers.

(3) Nutritive sweeteners.

(4) Characterizing flavoring ingredients (with or without coloring) as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Natural and artificial food flavoring.

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970, section 16.114 under "Fat, Roese-Gottlieb Method—Official Final Action."[2]

(d) *Nomenclature.* (1) The name of the food is "Heavy cream" or alternatively "Heavy whipping cream". The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in § 101.22 of this chapter. The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name:

(i) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(ii) The word "sweetened" if no characterizing flavoring ingredients are used, but nutritive sweetener is added.

(2) The following terms may appear on the label:

(i) The word "pasteurized" if the food has been pasteurized.

(ii) The word "homogenized" if the food has been homogenized.

(e) *Label declaration.* When used in the food, each of the ingredients specified in paragraph (b) of this section shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 131.155 Light cream.

(a) *Description.* Light cream is cream which contains not less than 18 percent but less than 30 percent milkfat. It is pasteurized or ultra-pasteurized, and may be homogenized.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Stabilizers.

(2) Emulsifiers.

(3) Nutritive sweeteners.

(4) Characterizing flavoring ingredients (with or without coloring) as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Natural and artificial food flavoring.

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970, section 16.114 under "Fat, Roese-Gottlieb Method—Official Final Action."[2]

(d) *Nomenclature.* The name of the food is "Light cream", or alternatively "Coffee cream" or "Table cream". The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name:

(i) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(ii) The word "sweetened" if no characterizing flavoring ingredients are used, but nutritive sweetener is added.

(2) The following terms may appear on the label:

(i) The word "pasteurized" if the food has been pasteurized.

(ii) The word "homogenized" if the food has been homogenized.

(e) *Label declaration.* When used in the food, each of the ingredients specified in paragraph (b) of this section shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 131.157 Light whipping cream.

(a) *Description.* Light whipping cream is cream which contains not less than 30 percent but less than 36 percent milkfat. It is pasteurized or ultra-pasteurized, and may be homogenized.

(b) *Optional ingredients.* The following safe and suitable optional ingredients may be used:

(1) Emulsifiers.

(2) Stabilizers.

(3) Nutritive sweeteners.

(4) Characterizing flavoring ingredients (with or without coloring) as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Natural and artificial food flavoring.

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970, section 16.114 under "Fat, Roese-Gottlieb Method—Official Final Action."[2]

(d) *Nomenclature.* The name of the food is "Light whipping cream" or alternatively "Whipping cream". The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name:

(i) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(ii) The word "sweetened" if no characterizing flavoring ingredients are used, but nutritive sweetener is added.

(2) The following terms may appear on the label:

(i) The word "pasteurized" if the food has been pasteurized.

(ii) The word "homogenized" if the food has been homogenized.

(e) *Label declaration.* When used in the food, each of the ingredients specified in paragraph (b) of this section shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 131.160 Sour cream.

(a) *Description.* Sour cream results from the souring, by lactic acid producing bacteria, of pasteurized cream. Sour cream contains not less than 18 percent

[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

milkfat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of the milkfat is not less than 18 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 14.4 percent milkfat. Sour cream has a titratable acidity of not less than 0.5 percent, calculated as lactic acid.

(b) *Optional ingredients.* (1) Safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product.

(2) Sodium citrate in an amount not more than 0.1 percent may be added prior to culturing as a flavor precursor.

(3) Rennet.

(4) Safe and suitable nutritive sweeteners.

(5) Salt.

(6) Flavoring ingredients, with or without safe and suitable coloring, as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Safe and suitable natural and artificial food flavoring.

(c) *Method of analysis.* Referenced methods in paragraphs (c) (1) and (2) of this section are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.[2]

(1) Milkfat content—"Fat—Official Final Action," section 16.129.

(2) Titratable acidity — "Acidity — Official Final Action," section 16.022.

(d) *Nomenclature.* The name of the food is "Sour cream" or alternatively "Cultured sour cream". The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any flavoring that characterizes the product, as specified in § 101.22 of this chapter. If nutritive sweetener in an amount sufficient to characterize the food is added without addition of characterizing flavoring, the name of the food shall be preceded by the word "sweetened".

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, e.g., "cultured cream".

§ 131.162 Acidified sour cream.

(a) *Description.* Acidified sour cream results from the souring of pasteurized cream with safe and suitable acidifiers, with or without addition of lactic acid producing bacteria. Acidified sour cream contains not less than 18 percent milkfat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of milkfat is not less than 18 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 14.4 percent milkfat. Acidified sour cream has a titratable acidity of not less than 0.5 percent, calculated as lactic acid.

(b) *Optional ingredients.* (1) Safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product.

(2) Rennet.

(3) Safe and suitable nutritive sweeteners.

(4) Salt.

(5) Flavoring ingredients, with or without safe and suitable coloring, as follows:

(i) Fruit and fruit juice, including concentrated fruit and fruit juice.

(ii) Safe and suitable natural and artificial food flavoring.

(c) *Method of analysis.* Referenced methods in paragraph (c) (1) and (2) of this section are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.[2]

(1) Milkfat content—"Fat—Official Final Action," section 16.129.

(2) Titratable acidity—"Acidity—Official Final Action," section 16.022.

(d) *Nomenclature.* The name of the food is "Acidified sour cream". The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any flavoring that characterizes the product, as specified in § 101.22 of this chapter. If nutritive sweetener in an amount sufficient to characterize the food is added without addition of characterizing flavoring, the name of the food shall be preceded by the word "sweetened".

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, e.g., "cultured cream".

§ 131.164 Sour cream dressing.

(a) *Description.* Sour cream dressing is made in semblance of sour cream but does not comply with the standards of identity for either sour cream under § 131.160 or acidified sour cream under § 131.162. Sour cream dressing contains not less than 18 percent milkfat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of milkfat is not less than 18 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 14.4 percent milkfat. Sour cream dressing has a titratable acidity of not less than 0.5 percent, calculated as lactic acid. The blend of all ingredients used shall be pasteurized, except that volatile flavoring substances, enzymes, bacterial cultures, and acidifying agents may be added following pasteurization.

(b) *Optional ingredients.* Safe and suitable ingredients may be used in a quantity not greater than is reasonably required to accomplish their intended effect.

(c) *Method of analysis.* Referenced methods in paragraph (c) (1) and (2) of this section are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.[2]

(1) Milkfat content—"Fat—Official Final Action," section 16.129.

(2) Titratable acidity—"Acidity—Official Final Action," section 16.022.

(d) *Nomenclature.* The name of the food is "Sour cream dressing". The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any flavoring that characterizes the product, as specified in § 101.22 of this chapter. If nutritive sweetener in an amount sufficient to characterize the food is added without addition of characterizing flavoring, the name of the food shall be preceded by the word "sweetened".

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that:

(1) Bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, e.g., "cultured cream".

(2) Concentrated skim milk, nonfat dry milk, and reconstituted skim milk prepared by addition of water to concentrated skim milk or nonfat dry milk may be declared as "skim milk".

(3) Concentrated milk, dry whole milk, and reconstituted milk prepared by addition of water to concentrated milk or dry whole milk may be declared as "milk".

(4) Sweet cream buttermilk, concentrated sweet cream buttermilk, and dried sweet cream buttermilk, may be declared as "buttermilk".

(5) Cheese whey, concentrated cheese whey, and dried cheese whey may be declared as "whey".

NOTE.—§ 131.164 (formerly § 18.570) was stayed in its entirety at 40 FR 18549, Apr. 29, 1975.

§ 131.180 Half-and-half.

(a) *Description.* Half-and-half is the food consisting of a mixture of milk and cream which contains not less than 10.5 percent but less than 18 percent milkfat. It is pasteurized or ultra-pasteurized, and may be homogenized.

(b) *Optional ingredients.* The following safe and suitable optional ingredients may be used:

(1) Emulsifiers.

(2) Stabilizers.

(3) Nutritive sweeteners.

(4) Characterizing flavoring ingredients (with or without coloring) as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Natural and artificial food flavoring.

(c) *Methods of analysis.* The milkfat content is determined by the method

prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970, section 16.114 under "Fat, Roese-Gottlieb Method—Official Final Action." [1]

(d) *Nomenclature.* The name of the food is "Half-and-half". The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name:

(i) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(ii) The word "sweetened" if no characterizing flavor ingredients are used, but nutritive sweetener is added.

(2) The following terms may appear on the label:

(i) The word "pasteurized" if the food has been pasteurized.

(ii) The word "homogenized" if the food has been homogenized.

(e) *Label declaration.* When used in the food, each of the ingredients specified in paragraph (b) of this section shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 131.185 Sour half-and-half.

(a) *Description.* Sour half-and-half results from the souring, by lactic acid producing bacteria, of pasteurized half-and-half. Sour half-and-half contains not less than 10.5 percent but less than 18 percent milkfat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of milkfat is not less than 10.5 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 8.4 percent milkfat. Sour half-and-half has a titratable acidity of not less than 0.5 percent, calculated as lactic acid.

(b) *Optional ingredients.* (1) Safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product.

(2) Sodium citrate in an amount not more than 0.1 percent may be added prior to culturing as a flavor precursor.

(3) Rennet.

(4) Safe and suitable nutritive sweeteners.

(5) Salt.

(6) Flavoring ingredients, with or without safe and suitable coloring, as follows:

(i) Fruit and fruit juice, including concentrated fruit and fruit juice.

(ii) Safe and suitable natural and artificial food flavoring.

(c) *Method of analysis.* Referenced methods in paragraph (c) (1) and (2) of this section are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.[2]

(1) Milkfat content—"Fat—Official Final Action," § 16.129.

(2) Titratable acidity—"Acidity—Official Final Action," section 16.022.

(d) *Nomenclature.* The name of the food is "Sour half-and-half" or alternatively "Cultured sour half-and-half". The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any flavoring that characterizes the product, as specified in § 101.22 of this chapter. If nutritive sweetener in an amount sufficient to characterize the food is added without addition of characterizing flavoring, the name of the food shall be preceded by the word "sweentened".

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, e.g., "cultured cream".

§ 131.187 Acidified sour half-and-half.

(a) *Description.* Acidified sour half-and-half results from the souring of pasteurized half-and-half with safe and suitable acidifiers, and with or without addition of lactic acid producing bacteria. Acidified sour half-and-half contains not less than 10.5 percent but less than 18 percent milkfat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of milkfat is not less that 10.5 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 8.4 percent milkfat. Acidified sour half-and-half has a titratable acidity of not less than 0.5 percent, calculated as lactic acid.

(b) *Optional ingredients.* (1) Safe and suitable ingredients to improve texture, prevent syneresis, or extend the shelf life of the product.

(2) Rennet.

(3) Safe and suitable nutritive sweeteners.

(4) Salt.

(5) Flavoring ingredients, with or without safe and suitable coloring, as follows:

(i) Fruit and fruit juice, including concentrated fruit and fruit juice.

(ii) Safe and suitable natural and artificial food flavoring.

(c) *Methods of analysis.* Referenced methods in paragraph (c) (1) and (2) of this section are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.[2]

(1) Milkfat content—"Fat—Official Final Action," section 16.129.

(2) Titratable acidity—"Acidity—Official Final Action," section 16.022.

(d) *Nomenclature.* The name of the food is "Acidified sour half-and-half". The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any flavoring that characterizes the product, as specified in § 101.22 of this chapter. If nutritive sweetener in an amount sufficient to characterize the food is added without addition of characterizing flavoring, the name of the food shall be preceded by the word "sweetened".

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, e.g., "cultured cream".

§ 131.189 Sour half-and-half dressing.

(a) *Description.* Sour half-and-half dressing is made in semblance of sour half-and-half, but does not comply with the standards of identity for either sour half-and-half under § 131.185 or acidified sour half-and-half under § 131.187. Sour half-and-half dressing contains not less than 10.5 percent but less than 18 percent milkfat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of milkfat is not less than 10.5 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 8.4 percent milkfat. Sour half-and-half dressing has a titratable acidity of not less than 0.5 percent, calculated as lactic acid. The blend of all ingredients used shall be pasteurized, except that volatile flavoring substances, enzymes, bacterial cultures, and acidifying agents may be added following pasteurization.

(b) *Optional ingredients.* Safe and suitable ingredients may be used in a quantity not greater than is reasonably required to accomplish their intended effect.

(c) *Method of analysis.* Referenced methods in paragraph (c) (1) and (2) of this section are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.[2]

(1) Milkfat content—"Fat—Official Final Action," section 16.129.

(2) Titratable acidity—"Acidity—Official Final Action," section 16.022.

(d) *Nomenclature.* The name of the food is "Sour half-and-half dressing". The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any flavoring that characterizes the product, as specified in § 101.22 of this chapter. If nutritive sweetener in an amount sufficient to characterize the food is added without addition of characterizing flavoring, the name of the food shall be preceded by the word "sweetened".

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the

applicable sections of Part 101 of this chapter, except that:

(1) Bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, e.g., "cultured cream".

(2) Concentrated skim milk, nonfat dry milk, and reconstituted skim milk prepared by addition of water to concentrated skim milk or nonfat dry milk may be declared as "skim milk".

(3) Concentrated milk, dry whole milk, and reconstituted milk prepared by addition of water to concentrated milk or dry whole milk may be declared as "milk".

(4) Sweet cream buttermilk, concentrated sweet cream buttermilk, and dried sweet cream buttermilk may be declared as "buttermilk".

(5) Cheese whey, concentrated cheese whey, and dried cheese whey may be declared as "whey".

PART 133—CHEESES AND RELATED CHEESE PRODUCTS

Subpart A—General Provisions

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133.3 Definitions.
133.10 Notice to manufacturers, packers, and distributors of pasteurized blended cheese, pasteurized process cheese, cheese food, cheese spread, and related foods.

Subpart B—Requirements for Specific Standardized Cheese and Related Cheese Products

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133.165 Parmesan and reggiano cheese.
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133.169 Pasteurized process cheese.
133.170 Pasteurized process cheese with fruits, vegetables, or meats.
133.171 Pasteurized process pimento cheese.
133.173 Pasteurized process cheese food.
133.174 Pasteurized process cheese food with fruits, vegetables, or meats.
133.175 Pasteurized cheese spread.
133.176 Pasteurized cheese spread with fruits, vegetables, or meats.
133.178 Pasteurized neufchatel cheese spread with other foods.
133.179 Pasteurized process cheese spread.
133.180 Pasteurized process cheese spread with fruits, vegetables, or meats.
133.181 Provolone and pasta filata cheese.
133.182 Soft ripened cheeses.
133.183 Romano cheese.
133.184 Roquefort, sheep's milk blue-mold, and blue-mold cheese from sheep's milk.
133.185 Samsoe cheese.
133.186 Sap sago cheese.
133.187 Semisoft cheeses.
133.188 Semisoft part-skim cheeses.
133.189 Skim milk cheese for manufacturing.
133.190 Spiced cheeses.
133.191 Part-skim spiced cheeses.
133.193 Spiced, flavored standardized cheeses.
133.195 Swiss and emmentaler cheese.
133.196 Swiss cheese for manufacturing.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046 as amended, 1055–1056 as amended (21 U.S.C. 341, 371) unless otherwise indicated.

Subpart A—General Provisions

§ 133.3 Definitions.

For the purposes of this part, the phrase "safe and suitable" when used to describe ingredients of cheese or cheese products means that such ingredients shall be functionally suitable substances that are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act; or if they are food additives as so defined, they shall be used in conformity with regulations established pursuant to section 409 of the act.

§ 133.10 Notice to manufacturers, packers, and distributors of pasteurized blended cheese, pasteurized process cheese, cheese food, cheese spread, and related foods.

(a) Definitions and standards of identity have recently been promulgated under the authority of the Federal Food, Drug, and Cosmetic Act for a number of foods made in part from cheese, including pasteurized process cheese; pasteurized process cheese with fruits, vegetables, or meats; pasteurized blended cheese; pasteurized process cheese food; pasteurized process cheese spread, and related foods. These standards prescribe the name for each such food. The act requires that this name appear on the label. Many of these names consist of several words. In the past it has been the practice of some manufacturers to subordinate the words "pasteurized," "blended," "process," "food," and "spread" to give undue prominence to the word "cheese" and to words naming the variety of cheese involved.

(b) When placing the names of these foods on labels so as to comply with the requirements of section 403 (a), (f), and (g) of the act, all the words forming the name specified by a definition and standard of identity should be given equal prominence. This can readily be accomplished by printing the specified name of the food in letters of the same size, color, and style of type, and with the same background.

(c) Where the names of optional ingredients are required to appear on the label, the designations of all such ingredients should be given equal prominence. The names of the optional ingredients should appear prominently and conspicuously but should not be displayed with greater prominence than the name of the food. The word "contains" may precede the names of the optional ingredients, and when so used will not be considered as intervening printed matter between name of food and name of optional ingredients required to be placed on the label.

(d) Where a manufacturer elects to include a label statement of fat and moisture content, the declaration should be on the basis of the food as marketed. A fat declaration on a moisture-free basis is likely to be misleading, and should not be used in labeling.

Subpart B—Requirements for Specific Standardized Cheese and Related Products

§ 133.102 Asiago fresh and asiago soft cheese.

(a) Asiago fresh cheese, asiago soft cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 45 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 133.113(c). It is cured for not less than 60 days.

(b) Milk which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid producing bacteria, present in such milk or added thereto. Harmless artificial blue or green coloring in a quantity which neutralizes any natural yellow coloring in the curd may be added. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the milk, is added to set the milk to a semisolid mass. The mass is cut, stirred, and heated to promote and regulate separation of the

whey from the curd. The whey is drained off. When the curd is sufficiently firm it is removed from the kettle or vat, further drained for a short time, packed into hoops, and pressed. The pressed curd is salted in brine and cured in a well-ventilated room. During curing the surface of the cheese is occasionally rubbed with a vegetable oil. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of asiago fresh cheese may be added during the procedure in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) (1) For the purposes of this section, the word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(2) Such milk may be bleached by the use of benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate; but the weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, sufficient vitamin A is added to the curd to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(d) Asiago fresh cheese in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e) (1) (i) If asiago fresh cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(ii) If the milk is bleached, the label shall bear the statement "Milk bleached with benzoyl peroxide".

(2) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in this section, showing the optional ingredient used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 133.103 Asiago medium cheese.

Asiago medium cheese conforms to the definition and standard of identity and is subject to the requirements for label statement of optional ingredients prescribed by § 133.102 for asiago fresh cheese, except that it contains not more than 35 percent moisture, its solids contain not less than 45 percent of milk fat, and it is cured for not less than 6 months.

§ 133.104 Asiago old cheese.

Asiago old cheese conforms to the definition and standard of identity and is subject to the requirements for label statement of optional ingredients prescribed by § 133.102 for asiago fresh cheese, except that it contains not more than 32 percent moisture, its solids contain not less than 42 percent of milk fat, and it is cured for not less than 1 year.

§ 133.106 Blue cheese.

(a) Blue cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It is characterized by the presence of bluish-green mold throughout the cheese. It contains not more than 46 percent moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 133.113(c). It is not less than 60 days old.

(b) Milk, which may be pasteurized or clarified or both, which may be warmed, and which may be homogenized, is subjected to the action of harmless lactic-acid producing bacteria, present in such milk or added thereto. Harmless artificial green or blue coloring in a quantity which neutralizes any natural yellow coloring in the curd may be added. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the milk, is added to set the milk to a semisolid mass. The mass is cut into smaller portions and allowed to stand for a time. The mixed curd and whey is placed in forms permitting further drainage. While being placed in forms, spores of the mold *Penicillium roquefortii* are added. The forms are turned several times during drainage. When sufficiently drained, the shaped curd is removed from the forms and salted with dry salt or brine. Perforations are then made in the shaped curd, and it is held at a temperature of approximately 50° F, at 90 to 95 percent relative humidity, until the characteristic mold growth has developed. During storage the surface of the cheese may be scraped to remove surface growth of undesirable microorganisms. The rind of the cheese may be coated with a vegetable food fat or oil (which may be hydrogenated), or any combination of two or more such articles. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of blue cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk.

(2) Such milk may be bleached by the use of benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate; but the weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk being bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, vitamin A is added to the curd in such quantity as to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(3) Such milk may be adjusted by separating part of the fat therefrom or by adding one or more of the following: Cream, cream which has been treated in the manner provided in paragraph (c) (2) of this section, concentrated skim milk, nonfat dry milk, water sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(d) The food may have applied to its surface an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e) (1) If the milk used is bleached, the label shall bear the statement "milk bleached with benzoyl peroxide".

(2) If the food contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement "_____ added to retard surface mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(3) Whenever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed in this paragraph showing the optional ingredients used shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter.

§ 133.108 Brick cheese.

(a) Brick cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 44 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed

in § 133.113(c). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, is brought to a temperature of about 88° F and subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the milk, is added to set the milk to a semisolid mass. The mass is cut into cubes with sides approximately ⅜-inch long, and stirred and heated so that the temperature rises slowly to about 96° F. The stirring is continued until the curd is sufficiently firm. Part of the whey is then removed, and the mixture diluted with water or salt brine to control the acidity. The curd is transferred to forms, and drained. During drainage it is pressed and turned. After drainage the curd is salted, and the biological curing agents characteristic of brick cheese are applied to the surface. The cheese is then cured to develop the characteristics of brick cheese. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of brick cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Brick cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 5 micrograms when tested by the method prescribed in § 133.113(f).

(d) Brick cheese in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e)(1) If brick cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(2) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in this section, showing the optional ingredient used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 133.109 Brick cheese for manufacturing.

Brick cheese for manufacturing conforms to the definition and standard of identity for brick cheese prescribed by § 133.108, except that the milk is not pasteurized, curing is not required, and the provisions of paragraph (d) of that section do not apply.

§ 133.111 Caciocavallo siciliano cheese.

(a) Caciocavallo siciliano cheese is the food prepared from cow's milk or sheep's milk or goat's milk or mixtures of two or all of these and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It has a stringy texture, and is made in oblong shapes. It contains not more than 40 percent of moisture, and its solids contain not less than 42 percent milk fat, as determined by the methods prescribed in § 133.113(c). It is cured for not less than 90 days at a temperature of not less than 35° F.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial blue or green coloring in a quantity which neutralizes any natural yellow coloring in the curd may be added. Sufficient rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is cut, stirred, and heated so as to promote and regulate the separation of whey from curd. The whey is drained off, and the curd is removed to another vat containing hot whey, in which it is soaked for several hours. This whey is withdrawn, the curd is allowed to mat, and is cut into blocks. These are washed in hot whey until the desired elasticity is obtained. The curd is removed from the vat, drained, pressed into oblong forms, dried, and salted in brine, and cured. It may be paraffined. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of caciocavallo siciliano cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c)(1) For the purposes of this section, the word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any such concentrated or dried products used.

(2) Such milk may be bleached by the use of benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate; but the weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, sufficient vitamin A is added to the curd to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(d) Caciocavallo siciliano cheese in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e)(1) When caciocavallo siciliano cheese is made solely from cow's milk, the name of such cheese is "caciocavallo siciliano cheese". When made from sheep's milk or goat's milk or mixtures of these, or one or both of these with cow's milk, the name is followed by the words "made from _____", the blank being filled in with the name or names of the milks used, in order of predominance by weight.

(2)(i) If caciocavallo siciliano cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(ii) If the milk used is bleached, the label shall bear the statement, "Milk bleached with benzoyl peroxide".

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed by this section, showing the optional ingredient used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 133.113 Cheddar cheese.

(a) Cheddar cheese, cheese, is the food prepared from milk and other

ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 39 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in paragraph (c) of this section. If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the milk, is added to set the milk to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. The whey is drained off, and the curd is matted into a cohesive mass. The mass is cut into slabs, which are so piled and handled as to promote the drainage of whey and the development of acidity. The slabs are then cut into pieces, which may be rinsed by sprinkling or pouring water over them, with free and continuous drainage; but the duration of such rinsing is so limited that only the whey on the surface of such pieces is removed. The curd is salted, stirred, further drained, and pressed into forms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of cheddar cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) Determine moisture by the method prescribed on page 262 (15.124) [Ed. note, 10th edition, 1965, p. 247, sec. 15.157], under "Moisture—Official," and milk fat by the method prescribed on page 263 (15.131) [Ed. note, 10th edition, 1965, p. 248, sec. 15.164], under "Fat—Official," of "Official Methods of Analysis of the Association of Official Agricultural Chemists," Seventh Edition, 1950. Subtract the percent of moisture found from 100; divide the remainder into the percent milk fat found. The quotient, multiplied by 100, shall be considered to be the percent of milk fat contained in the solids.

(d) Cheddar cheese in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Cheddar cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in paragraph (f) of this section.

(3) During the cheese-making process the milk may be treated with hydrogen peroxide solution followed by addition of a suitable catalase preparation to eliminate the hydrogen peroxide. The hydrogen peroxide solution shall comply with the specifications of the United States Pharmacopeia, except that it may exceed the concentration specified therein and it does not contain added preservative. The amount of the hydrogen peroxide solution used shall be such that the weight of the hydrogen peroxide added thereby does not exceed 0.05 percent of the weight of the milk treated. The catalase preparation used shall be stable, and in potency, for eliminating added hydrogen peroxide from milk, it shall not be less than equivalent to liver-catalase preparation testing 100 Keil units per gram. It shall be either a preparation that is not a food additive within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act, or a preparation that it is a food additive but which is used in conformity with regulations promulgated pursuant to the authority of section 409 of the act. The amount of catalase preparation used shall be such that the weight of the catalase added thereby does not exceed 20 parts per million of the weight of the milk treated.

(f) The method referred to in paragraph (e)(2) of this section is as follows:

I. *Reagents*—1. *Buffers*—a. *Barium borate-hydroxide buffer.* Dissolve 25.0 gm. of c. p. barium hydroxide ($Ba(OH)_2 \cdot 8H_2O$, fresh, not deteriorated) in distilled water and dilute to 500 ml. Dissolve, in another flask or cylinder, 11.0 gm. of c. p., boric acid (H_2BO_3) and dilute to 500 ml. Warm each to 50° C (122° F), mix the two together, stir, cool to approximately 20° C (68° F), filter and stopper the filtrate tightly (pH approximately 10.6). The buffer prepared thus is designated as the 25–11 buffer, the figures indicating the grams per liter of each of the respective reagents.

b. *Color-development buffer.* Dissolve 6.0 gm. of sodium metaborate ($NaBO_2$) and 20 gm. of sodium chloride in water and dilute to a liter with water (pH 9.8).

c. *Color-dilution buffer.* Dilute 100 ml. of color-development buffer 1–b to a liter with water.

d. *Standard borax buffer, 0.01-molar, for checking pH meter, pH 9.18 at 25° C.*[1] Dissolve 0.9544 gm. of pure borax (Bureau of Standards Sample 187) in distilled water (distilled recently or freshly boiled and cooled) and dilute to 250 ml. Keep stoppered tightly.

2. *Buffer substrates.* Specify phenol-free crystalline disodium phenyl phosphate.

a. *For evaluating pasteurization.* Dissolve 0.10 gm. of the phenyl phosphate in 100 ml of the appropriate (table 1) barium borate-hydroxide buffer 1–a.

b. *For quantitative results with raw-milk cheese.* Dissolve 0.20 gm. of the phenyl phosphate in 100 ml. of the appropriate (table 1) barium borate-hydroxide buffer 1–a.

3. *Protein precipitants*—a. *Zinc-copper precipitant for unripened cheese.* Dissolve 6.0 gm. of zinc sulfate ($ZnSO_4 \cdot 7H_2O$) and 0.1 gm. of copper sulfate ($CuSO_4 \cdot 5H_2O$) in water and dilute to 100 ml. with water. The precipitant prepared thus is designated as the 6.0–0.1 precipitant.

b. *Zinc precipitant for ripened cheese.* Dissolve 6.0 gm. of zinc sulfate in water and dilute to 100 ml. with water. This precipitant is designated as the 6.0 precipitant.

4. *BQC (2,6-dibromoquinone-chloroimine solution) (Gibbs' reagent):* Dissolve 40 mg. of BQC powder in 10 ml. of absolute methyl alcohol and transfer to a dark-colored dropper bottle. This reagent remains stable for at least a month if kept in the ice tray of a refrigerator. Do not use it after it begins to turn brown.

5. *Other reagents*—a. *Copper sulfate, 0.05 percent, for standards.* Dissolve 0.05 gm of copper sulfate in water and dilute to 100 ml.

b. *Butyl alcohol.* Specify *n*-butyl alcohol, boiling point 116°–118° C. To adjust the pH, mix 50 ml. of the color-development buffer 1–b with a liter of the butyl alcohol.

6. *Phenol standards*—a. *Stock solution.* Weigh accurately 1.0 gm. of pure phenol, transfer to a liter volumetric flask, dilute to a liter with water, and mix. One ml. contains 1 mg. (0.001 gm.) of phenol. Use this stock solution to prepare standard solutions. It is stable for several months in the refrigerator.

b. *Preparation of standards.* Dilute 10.0 ml. of the stock solution 6–a to a liter with water, and mix. One ml. contains 10 micrograms (0.00001 gm., 10 gammas, or 10 units) of phenol. Use this standard solution to prepare more dilute standard solutions; e.g., dilute 5, 10, 30, and 50 ml. to 100 ml. with water to prepare standard solutions containing 0.5, 1.0, 3.0, and 5.0 gammas or units of phenol per milliliter, respectively. Keep standard solutions in the refrigerator.

In a similar manner, prepare from the stock solution such more concentrated standard solutions as may be needed, containing, for example, 20, 30, and 40 units per milliliter.

Measure appropriate quantities of the phenol standard solution into a series of tubes (preferably graduated at 5.0 and 10.0 ml.) to provide a suitable range of standards as needed, containing 0 (control blank), 0.5, 1.0, 3.0, 5.0, 10.0, etc., to 30 or 40 units. To increase the brightness of the blue color and improve the stability of the standards add 1.0 ml. of 0.05 percent copper sulfate solution 5–a to each.

Add 5.0 ml. of color dilution buffer 1–c and add water to bring the volume to 10.0 ml. Add 4 drops (0.08 ml.) of BQC 4, mix, and allow to develop for 30 minutes at room temperature. If the butyl alcohol extraction method is to be used in the test, extract the standards as described under III Conducting the Test.

Read the color intensities with a photometer, subtract the value of the blank from the value of each phenol standard, and prepare a standard curve (straight line). When the standards are to be used for visual comparisons they should be stored in a refrigerator.

[1] All pH values reported herein were determined at 25° C or corrected to that temperature.

TABLE I.—*Phosphatase test modifications for different kinds of cheese and cheese of different ages*

Kind of cheese	Age or extent of curing; other details	Buffer for optimal pH (9.85–10.20)	Precipitant
Cheddar, granular, stirred curd, hard cheese	1 week	[1] 25–11	[2] 6.0–0.0
	1 week–1½ mo	25–11	[3] 6.0
	1½–4 mo	26–11	6.0
	4 mo	27–11	6.1
Washed curd, soaked curd, colby	1 week	25–11	6.0–0.0
	1 week–2 mo	26–11	6.0
	2 mo	26–11	6.0
Swiss, gruyere	1 week	25–11	6.0–0.1
	1 week–1 mo	25–11	6.1
	1–3 mo	26–11	6.0
	3 mo	27–11	6.1
Brick, muenster	1 week	25–11	6.0–0.0
	1 week–1 mo	25–11	6.1
	1–2 mo	25–11	6.0
	2 mo	26–11	6.0
Edam, gouda	1 week	25–11	6.0–0.1
	1 week–2 mo	25–11	6.0–0.1
	2–4 mo	26–11	6.0
	4 mo	27–11	6.0
Blue mold, blue	1 week	25–11	6.0–6.1
	1 week–1 mo	26–11	6.0
	1–4½ mo	27–11	6.0
	4½ mo	28–11	6.0
Camembert, limburger	1 week	25–11	6.0–0.1
	1 week–1 mo	25–11	6.0
	1–2 mo	26–11	6.0
	2 mo	27–11	6.0
Monterey	1 week	25–11	6.0–0.1
	1 week–2 mo	25–11	6.0
	2 mo	26–11	6.0
High-moisture jack	1 week	25–11	6.0–0.1
	1 week–2½ mo	25–11	6.1
	2½ mo	26–11	6.1
Provolone, pasta filata	1 week	25–11	6.0–0.0
	1 week–1 mo	25–11	6.0
	1–3 mo	26–11	6.0
	3 mo	27–11	6.0
Parmesan, reggiano, monte, modena, romano, asiago old.	1 week	25–11	6.0–0.0
	1 week–2 mo	26–11	6.0
	2–6 mo	27–11	6.0
	6 mo–1 yr	28–11	6.0
	1 yr	29–11	6.0
Asiago fresh	Same as cheddar		
Asiago medium	1 week	25–11	6.0–0.1
	1 week–1 mo	25–11	6.0
	1–3 mo	26–11	6.0
	3 mo	27–11	6.0
Gorgonzola	Same as blue		
Cottage, cook cheese, koch kaese	Dry	25–11	6.0–0.1
	Moist	[4] 25–11(8+2)	4.5–0.1
Cream cheese		25–11(7+3)	6.0–0.1
Semisoft cheese	1 week	25–11	6.0–0.1
	1 week–1 mo	25–11	6.0
	1 mo	26–11	6.0
Soft ripened cheese	1 week	25–11	6.0–0.1
	1 week–1 mo	25–11	6.0
	1 mo	26–11	6.0
Nokkelost, kuminost, sage cheese	1 week	25–11	6.0–0.1
	1 week–1¼ mo	25–11	6.0
	1¼–4 mo	26–11	6.0
	4 mo	27–11	6.0
Pasteurized process, pasteurized process pimento, pasteurized process with fruits, meats, etc.	Soft, mild	25–11	6.0
	Medium, firm	26–11	6.0
	Firm, sharp (including swiss, gruyere)	27–11	6.0
Pasteurized process cheese foods; pasteurized process cheese foods with fruits, meats, etc.	Same as pasteurized process		
Pasteurized process cheese spreads; pasteurized process cheese spreads with fruits, meats, etc.	Soft, high moisture, including cream spreads.	25–11	6.0
	Less soft, including blue	26–11	6.0
Cold-pack, club; cold-pack cheese foods; cold-pack cheese foods with fruits, meats, etc.	Mild to medium flavored, soft	26–11	6.0
	Sharp, firm	27–11	6.0

[1] Grams $Ba(OH)_2.8H_2O$ and H_3BO_3 per liter, respectively.
[2] Grams $ZnSO_4.7H_2O$ and $CuSO_4.5H_2O$ per 100 ml., respectively.
[3] Grams $ZnSO_4.7H_2O$ per 100 ml.
[4] 8 parts of 25–11 buffer plus 2 parts o. water.

II. *Sampling*—1. *Hard cheese.* Take a sample from the interior with a *clean* Roquefort trier, place in a small tube, stopper the tube, and keep it in a refrigerator.

2. *Soft and semisoft ripened cheese.* Harden the cheese by chilling it in the freezing chamber of a refrigerator. Taking special precaution to avoid contaminating the sample with phosphatase that may be present on the surface, use either of the following methods for sampling:

a. Cut a portion from the end of the loaf or from the side of the cheese, extending in at least 2 inches if possible, or to a point somewhat beyond the center in the case of a small cheese. Cut a slit ¼ to ½ inch deep at least halfway around the portion and midway between the top and bottom. Break the portion into two parts, pulling it apart so that it breaks on a line with the slit, being careful not to contaminate the freshly exposed, broken surface. Remove the sample from the freshly exposed surface at or near the center of the cheese.

b. Remove the surface of the area to be sampled—e.g., the end and the adjacent sides—with a clean knife or spatula, to a depth of ¼ inch. Clean the instrument and hands with hot water and phenol-free soap and wipe them dry. Remove the freshly exposed surface to a similar or greater depth and repeat the cleaning. Then take the sample from the center of the freshly exposed area, preferably at or near the center of the cheese in the case of a small cheese.

3. *Process cheese, spreads, etc.* Take the sample from beneath the surface with a clean knife or spatula.

Avoid the use of samples contaminated with mold.

4. *Preservation.* If a preservative is necessary, put 1 to 3 ml. of chloroform in the container, cover with a plug of cotton, insert sample and stopper container tightly. Label preserved samples "*Poison* — Preservative added."

III. *Conducting the test.* 1. Weigh, on a clean balance pan or watch glass, a 0.50-gm. sample (preferably two samples in duplicate) and place in a culture tube 16 or 18 x 150 mm. Similarly, weigh another sample and place in a tube as a control or blank. If the cheese is sticky, weigh the sample on a piece of wax paper about 1 x 1 inch and insert the paper with the sample into the tube. Macerate the blank and the test with a glass rod about 8 x 180 mm.

2. Add to the blank 1.0 ml. of the appropriate (Table 1) barium buffer 1-a (without substrate added), macerate with the rod, leave the rod in the tube, heat for about a minute to at least 85° C (185° F) in a beaker of boiling water with the beaker covered so that the entire tube becomes heated to approximately 85° C, cool to room temperature, and macerate again with the rod.

3. Add to the test 1.0 ml. of the appropriate (Table 1) barium buffer-substrate 2-a or 2-b, and macerate.

From this point, treat the blank and the test in a similar manner.

Add 9.0 ml. of the appropriate barium buffer substrate 2-a or 2-b (total, 10.0 ml. added), and mix. The rod may be left in the tube during incubation; or, if removing it at this point, cut a piece of filter paper approximately 1 x 1 inch, wrap and hold it tightly around the rod, rotate the rod while withdrawing it from within the tube so as to wipe the rod clean, insert the paper with the adhering fat into the tube, and stopper the tube.

4. Incubate in a water bath at 37°–38° C (99°–100° F) for 1 hour, mixing or shaking the contents occasionally.

5. Place in a beaker of boiling water for nearly a minute, heating to 85° C (185° F), and cool to room temperature.

6. Pipet in 1.0 ml. of the zinc precipitant 3–b for ripened cheese or the zinc-copper precipitant 3–a for unripened cheese, and mix thoroughly (pH of mixture, 9.0–9.1).

7. Filter (5-cm. funnel, 9-cm. Whatman No. 42 or No. 2 paper recommended), and collect 5.0 ml. of filtrate in a tube, preferably graduated at 5.0 and 10.0 ml.

8. Add 5.0 ml. of color-development buffer 1–b (pH of mixture, 9.3–9.4).

9. Add four drops [3] of BQC 4, mix, and allow the color to develop for 30 minutes at room temperature.

10. Determine the amount of blue color by either of two methods:

a. *With a photometer.* Read the color intensity of the blank and that of the test, subtract the reading of the blank from that of the test, and convert the result into phenol equivalents by reference to the standard curve described under "Phenol standards." The butyl alcohol extraction method is ordinarily unnecessary when using a photometer.

b. *With visual standards.* For quantitative results in borderline instances, e.g., tests yielding 0.5 to 5 units of color, extract with butyl alcohol 5–b. Add 5.0 ml. of the alcohol and invert the tube slowly several times. Centrifuge if necessary to increase the clearness of the alcohol layer. Compare the blue color with the colors of standards in the alcohol.

[3] For merely detecting underpasteurization, in testing unripened cheese, two drops is sufficient, provided the visual standards are prepared likewise with two drops.

With samples yielding more than 5 units, compare the colors in aqueous tests with those of aqueous standards.

11. *Dilution method for quantitative results.* In tests that are observed during color development to be strongly positive, e.g., 20 units or more, in which four drops of BQC may be much less than sufficient to combine with all of the phenol, pipet an appropriate proportion of the contents into another tube, make up to 10.0 ml. with color-dilution buffer 1–c, and add two drops more of BQC in the case of unripened cheese or four drops in the case of ripened cheese. With each test, dilute and treat the blank in the corresponding manner. Dilute each strongly positive test thus until the final color is within the range of the standards or photometer. Allow 30 minutes for color development after the last addition of BQC, and make the reading at the end of the 30-minute period. Multiply, for example, by 2 for a 5+5 dilution, 10 for a 1+9 dilution, and 50 for a 1+9 followed by a 2+8 dilution.

Alternatively, to reduce the amount of yellow off color, add two instead of four drops of BQC after each dilution, and allow the color to develop. Then test the completeness of color development by adding a third drop; repeat the dilution procedure until the addition of an extra drop does not cause any further increase in the amount of blue color.

12. *Calculation and evaluation of results.* When using 0.5 gm. of sample and adding a total of 11.0 ml. of liquid, multiply the value of the reading by 1.1 to convert it to units of color or phenol equivalents per 0.25 gm. of cheese. The result may, if desired, be converted to phenol equivalents per 1 gm. by multiplying by 4.4.

IV. *Photometric determination.* To read the color in aqueous solution, use a filter with maximum light transmission in the region of 610 $m\mu$ wave length.

To read the color in butyl alcohol, extract the color as described above. If necessary, centrifuge the sample for 5 minutes to break the emulsion and to remove the moisture suspended in the alcohol layer. A Babcock centrifuge can be adapted for this purpose by making special tube holders as follows: Slice a section ¼ inch thick from a rubber stopper of suitable diameter to fit in the bottom of the centrifuge cup. Glue together two cork stoppers of appropriate diameter, bore through the center a hole of proper size to hold the tube snugly, and insert the double-cork section into the cup. After centrifuging, remove nearly all of the butyl alcohol by means of a pipet with a rubber bulb on the top end. Filter the alcohol into the photometer cell and read with a filter with maximum light transmission in the region of 650 $m\mu$ wave length.

If more than approximately 4 ml. of butyl alcohol is required for the photometer used, conduct the test in a larger tube and extract the color, in both the test and the standards, with the necessary quantity of butyl alcohol rather than with 5 ml. specified above.

V. *Precautions.* The length of time that the crystalline disodium phenyl phosphate and the BQC powder will remain stable can be increased greatly by keeping them in the freezing chamber of a refrigerator, and by keeping them dry.

The glassware, stoppers, and sampling tools should be scrupulously clean, and it is desirable to soak them in hot, running water after cleaning.

The solid barium hydroxide and the barium buffer must be kept stoppered tightly to prevent absorption of carbon dioxide. Phenolic contamination from plastic closures on reagent bottles has been encountered, and therefore the use of plastic closures should be avoided. Rubber stoppers should not be used in flasks in which butyl alcohol is stored. Glass or cork stoppers should be used.

VI. *Modifications for different cheeses.* Different kinds of cheese and cheeses of different ages have different buffering capacities, and therefore some of them require modification of concentrations of the reagents. The modifications of the barium buffer needed to produce optimal pH conditions during incubation (9.85–10.20), and of the precipitant to yield uniformly clear filtrates and to minimize interference during color development under optimal pH conditions (9.3–9.4), are specified in Table I.

With some samples, especially those of unknown history, slight deviations from the optimal pH range may occur, but such deviations do not very materially affect the results. For example, pH values as low as 9.6 or as high as 10.35 during incubation have been found to result in an average decrease of not more than 20 percent below the maximum in the quantity of phenol liberated. The use of the 25–11 buffer substrate with samples for which the 27–11 buffer substrate is specified yields pH values not lower than 9.8.

In testing cheese of unknown history or age, information as to the percentage of solids, especially the nonfat solids, is useful as an indication of the correct buffer to use; cheese with a relatively high percentage of nonfat solids generally requires the use of a relatively concentrated buffer to adjust the pH of the mixture correctly.

For precise quantitative results on unknown samples, adjust the pH to 10.0–10.05 for the incubation.

Cottage cheese curd is heated in the presence of considerable acid during manufacture, and therefore its phosphatase values are comparatively low. Alternatively, to increase the sensitivity of the test on cottage cheese, apply the following modifications: Use a 1.0-gm. sample, 27–11 buffer substrate, 2-hour incubation, and 6.0–0.1 precipitant.

(g)(1) If cheddar cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used; e.g., "Sorbic acid and potassium sorbate added to retard mold growth".

(2) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in this section, showing the optional ingredient used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 133.114 Cheddar cheese for manufacturing.

Cheddar cheese for manufacturing conforms to the definition and standard of identity prescribed for cheddar cheese by § 133.113, except that the milk is not pasteurized, curing is not required, and the provisions of paragraph (d) of that section do not apply.

§ 133.116 Low sodium cheddar cheese.

Low sodium cheddar cheese is the food prepared from the same ingredients and in the same manner prescribed in § 133.113 for cheddar cheese and complies with all the provisions of § 133.113, including the requirements for label statement of optional ingredients, except that:

(a) Salt is not used. Any safe and suitable ingredient or combination of ingredients that contains no sodium and that is recognized as a salt substitute may be used.

(b) Sodium sorbate is not used.

(c) It contains not more than 96 milligrams of sodium per pound of finished food.

(d) The name of the food is "low sodium cheddar cheese". The letters in the words "low sodium" shall be of the same size and style of type as the letters in the words "cheddar cheese", wherever such words appear on the label.

(e) If a salt substitute as provided for in paragraph (a) of this section is used, the label shall bear the statement "_____ added as a salt substitute", the blank being filled in with the common name or names of the ingredient or ingredients used as a salt substitute.

(f) Low sodium cheddar cheese is subject to § 105.69 of this chapter.

§ 133.118 Colby cheese.

(a) Colby cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 40 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 133.113(c). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficent rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the milk, is added to set the milk to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. A part of the whey is drained off, and the curd is cooled by adding water, the stirring being continued so as to prevent the pieces of curd from matting. The curd is drained, salted, stirred, further drained, and pressed into forms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of colby cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk, water, in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Colby cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 133.113(f).

(3) During the cheese-making process the milk may be treated as provided in § 133.113 (e) (3).

(d) (1) Colby cheese in the form of slices or cuts may have added to it a clear aqueous solution prepared by condensing or precipitating wood smoke in water.

(2) Colby cheese in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight calculated as sorbic acid.

(e) (1) If colby cheese has added to it a clear aqueous solution prepared by condensing or precipitating wood smoke in water as provided in paragraph (d) (1) of this section, the name of the food is immediately followed by the words "with added smoke flavoring" with all words in this phrase of the same type size, style, and color without intervening written, printed, or graphic matter.

(2) If colby cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d) (2) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in paragraph (e) (2) of this section, showing the optional ingredient used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter except for the statement "with added smoke flavoring," as set forth in paragraph (e) (1) of this section.

§ 133.119 Colby cheese for manufacturing.

Colby cheese for manufacturing conforms to the definition and standard of identity prescribed for colby cheese by § 133.118, except that the milk is not pasteurized, curing is not required, and the provisions of paragraph (d) of that section do not apply.

§ 133.121 Low sodium colby cheese.

Low sodium colby cheese is the food prepared from the same ingredients and in the same manner prescribed in § 133.118 for colby cheese and complies with all the provisions of § 133.118, including the requirements for label statement of optional ingredients, except that:

(a) Salt is not used. Any safe and suitable ingredient or combination of ingredients that contains no sodium and that is recognized as a salt substitute may be used.

(b) Sodium sorbate is not used.

(c) It contains not more than 96 milligrams of sodium per pound of finished food.

(d) The name of the food is "low sodium colby cheese". The letters in the words "low sodium" shall be of the same size and style of type as the letters in the words "colby cheese", wherever such words appear on the label.

(e) If a salt substitute as provided for in paragraph (a) of this section is used, the label shall bear the statement "_____ added as a salt substitute", the blank being filled in with the common name or names of the ingredient or ingredients used as a salt substitute.

(f) Low sodium colby cheese is subject to § 105.69 of this chapter.

§ 133.123 Cold-pack and club cheese.

(a) (1) Cold-pack cheese, club cheese, is the food prepared by comminuting, without the aid of heat, one or more cheeses of the same or two or more varieties, except cream cheese, neufchatel cheese, cottage cheese, lowfat cottage cheese, cottage cheese dry curd, hard grating cheese, semisoft part-skim cheese, part-skim spiced cheese and skim milk cheese for manufacturing, into a homogeneous plastic mass. One or more of the optional ingredients designated in paragraph (c) of this section may be used.

(2) All cheeses used in a cold-pack cheese are made from pasteurized milk or are held for not less than 60 days at a temperature of not less than 35° F before being comminuted.

(3) (i) The moisture content of a cold-pack cheese made from a single variety of cheese is not more than the maximum moisture content prescribed by the definition and standard of identity, if any there be, for the variety of cheese used. If there is no applicable definition and standard of identity, or if such standard contains no provision as to maximum moisture content, no water is used in the preparation of the cold-pack cheese.

(ii) The fat content of the solids of a cold-pack cheese made from a single variety of cheese is not less than the minimum prescribed by the definition and standard of identity, if any there be, for the variety of cheese used, but in no case is less than 47 percent, except that the fat content of the solids of cold-pack swiss cheese is not less than 43 percent, and the fat content of the solids of cold-pack gruyere cheese is not less than 45 percent.

(4) (i) The moisture content of a cold-pack cheese made from two or more varieties of cheese is not more than the arithmetical average of the maximum moisture contents prescribed by the definitions and standards of identity, if any there be, for the varieties of cheese used, but in no case is the moisture content more than 42 percent, except that the moisture content of a cold-pack cheese made from two or more of the varieties cheddar cheese, washed curd cheese, colby cheese, and granular cheese is not more than 39 percent.

(ii) The fat content of the solids of a cold-pack cheese made from two or more varieties of cheese is not less than the arithmetical average of the minimum percent of fat prescribed by the definitions and standards of identity, if any there be, for the varieties of cheese used, but in no case is less than 47 percent, except that the fat content of the solids of a cold-pack cheese made from swiss cheese and gruyere cheese is not less than 45 percent.

(5) Moisture and fat are determined by the methods prescribed in § 133.113(c).

(6) The weight of each variety of cheese in a cold-pack cheese made from two varieties of cheese is not less than 25 percent of the total weight of both, except that the weight of blue cheese, nuworld cheese, roquefort cheese, or gorgonzola cheese is not less than 10 percent of the total weight of both, and the weight of limburger cheese is not less than 5 percent of the total weight of both. The weight of each variety of cheese in a cold-pack cheese made from three or more varieties of cheese is not less than 15 percent of the total weight of all, except that the weight of blue cheese, nuworld cheese, roquefort cheese, or gorgonzola cheese is not less than 5 percent of the total weight of all, and the weight of limburger cheese is not less than 3 percent of the total weight of all. These limits do not apply to the quantity of cheddar cheese, washed curd cheese, colby cheese, and granular cheese in mixtures which are designated as "American cheese" as prescribed in paragraph (d) (2) of this section. Such mixtures are considered as one variety of cheese for the purpose of this paragraph (a) (6).

(b) Cold-pack cheese may be smoked, or the cheese or cheeses from which it is made may be smoked, before comminuting and mixing, or it may contain substances prepared by condensing or precipitating wood smoke.

(c) The optional ingredients referred to in paragraph (a) of this section are:

(1) An acidifying agent consisting of one or any mixture of two or more of the following: A vinegar, lactic acid, citric acid, acetic acid, and phosphoric acid, in such quantity that the pH of the finished cold-pack cheese is not below 4.5. For the purposes of this section vinegar is considered to be acetic acid.

(2) Water.

(3) Salt.

(4) Harmless artificial coloring.

(5) Spices or flavorings, other than any which singly or in combination with other ingredients simulate the flavor of a cheese of any age or variety.

(6) Cold-pack cheese in consumer-sized packages may contain an optional

mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid or consisting of not more than 0.3 percent by weight of sodium propionate, calcium propionate, or a combination of sodium propionate and calcium propionate.

(d) (1) The name of a cold-pack cheese for which a definition and standard of identity is prescribed by this section is "Cold-pack _____ cheese", "_____ cold-pack cheese" or "_____ club cheese", the blanks being filled in with the name or names of the varieties of cheese used, in order of predominance by weight.

(2) If the cold-pack cheese is made of cheddar cheese, washed curd cheese, colby cheese, or granular cheese or any mixture of two or more of these, it may be designated "Cold-pack American cheese"; or when cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these is combined with other varieties of cheese in the cheese ingredient any of such cheeses or such mixture may be designated as "American cheese".

(3) The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. Wherever any word or statement emphasizing the name of any ingredient appears on the label (other than in an ingredient statement as specified in paragraph (f) of this section) so conspicuously as to be easily seen under customary conditions of purchase, the full name of the food shall immediately and conspicuously precede or follow such word or statement in type of at least the same size as the type used in such word or statement.

(e) The name of the food shall include a declaration of any flavoring, including smoke and substances prepared by condensing or precipitating wood smoke, that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice that characterizes the product.

(f) The common name of each of the ingredients used shall be declared on the labels as required by the applicable sections of Part 101 of this chapter, except that:

(1) Artificial coloring need not be declared.

(2) If the cheese ingredient contains cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these, such cheese of such mixture may be designated as "American cheese".

§ 133.124 Cold-pack cheese food.

(a) (1) Cold-pack cheese food is the food prepared by comminuting and mixing, without the aid of heat, one or more of the optional cheese ingredients prescribed in paragraph (c) of this section, with one or more of the optional dairy ingredients prescribed in paragraph (d) of this section, into a homogeneous plastic mass. One or more of the optional ingredients specified in paragraph (c) of this section may be used.

(2) All cheeses used in a cold-pack cheese food are made from pasteurized milk, or are held for not less than 60 days at a temperature of not less than 35° F before being comminuted.

(3) The moisture content of a cold-pack cheese food is not more than 44 percent, and the fat content is not less than 23 percent.

(4) Moisture and fat are determined by the methods prescribed in § 133.113 (c), except that in determining moisture the loss in weight which occurs in drying for 5 hours, under the conditions prescribed in such method, is taken as the weight of moisture.

(5) The weight of the cheese ingredient prescribed by paragraph (a) (1) of this section constitutes not less than 51 percent of the weight of the finished cold-pack cheese food.

(6) The weight of each variety of cheese in the cold-pack cheese food made with two varieties of cheese is not less than 25 percent of the total weight of both, except that the weight of blue cheese, nuworld cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 10 percent of the total weight of both. The weight of each variety of cheese in the cold-pack cheese food made with three or more varieties of cheese is not less than 15 percent of the total weight of all, except that the weight of blue cheese, nuworld cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 5 percent of the total weight of all. These limits do not apply to the quantity of cheddar cheese, washed curd cheese, colby cheese, and granular cheese in mixtures which are designated as "American cheese" as prescribed in paragraph (h) (5) of this section. Such mixtures are considered as one variety of cheese for the purposes of this paragraph (a) (6).

(b) Cold-pack cheese food may be smoked, or the cheese or cheeses from which it is made may be smoked, before comminuting and mixing, or it may contain substances prepared by condensing or precipitating wood smoke.

(c) The optional cheese ingredients referred to in paragraph (a) of this section are: One or more cheeses of the same or two or more varieties, except that cream cheese, neufchatel cheese, cottage cheese, creamed cottage cheese, cook cheese, and skim-milk cheese for manufacturing are not used, and except that semisoft part-skim cheese, part-skim spiced cheese, and hard grating cheese may not be used, alone or in combination with each other, as the cheese ingredient.

(d) The optional dairy ingredients referred to in paragraph (a) of this section are: Cream, milk, skim milk, buttermilk, cheese whey, any of the foregoing from which part of the water has been removed, anhydrous milkfat, dehydrated cream, skim milk cheese for manufacturing, and albumin from cheese whey. All optional dairy ingredients used in cold-pack cheese food are pasteurized or made from products that have been pasteurized.

(e) The other optional ingredients referred to in paragraph (a) of this section are:

(1) An acidifying agent consisting of one or any mixture of two or more of the following: A vinegar, lactic acid, citric acid, acetic acid, and phosphoric acid, in such quantity that the pH of the finished cold-pack cheese food is not below 4.5.

(2) Water.

(3) Salt.

(4) Harmless artificial coloring.

(5) Spices or flavorings, other than any which singly or in combination with other ingredients simulate the flavor of cheese of any age or variety.

(6) A sweetening agent consisting of one or any mixture of two or more of the following: Sugar, dextrose, corn sugar, corn sirup, corn sirup solids, glucose sirup, glucose sirup solids, maltose, malt sirup, and hydrolyzed lactose, in a quantity necessary for seasoning.

(7) Cold-pack cheese food in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid or consisting of not more than 0.3 percent by weight of sodium propionate, calcium propionate, or a combination of sodium propionate and calcium propionate.

(8) In the preparation of cold-pack cheese food, guar gum, or xanthan gum, or both may be used, but the total quantity of such ingredient or combination is not to exceed 0.3 percent of the weight of the finished food. When one or both such optional ingredients is used, dioctyl sodium sulfosuccinate complying with the requirements of § 172.810 of this chapter may be used in a quantity not in excess of 0.5 percent by weight of such ingredient or ingredients.

(f) The name of the food is "cold-pack cheese food". The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. Wherever any word or statement emphasizing the name of any ingredient appears on the label (other than in an ingredient statement as specified in paragraph (h) of this section) so conspicuously as to be easily seen under customary conditions of purchase, the full name of the food shall immediately and conspicuously precede or follow such word or statement in type of at least the same size as the type used in such word or statement.

(g) The name of the food shall include a declaration of any flavoring, including smoke and substances prepared by condensing or precipitating wood smoke, that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice that characterizes the product.

(h) The common name of each of the ingredients used shall be declared on the label as required by the applicable sec-

tions of Part 101 of this chapter, except that:

(1) Plastic cream and dried cream may be declared as "cream".

(2) Concentrated milk and dried milk may be declared as "milk".

(3) Concentrated skim milk and nonfat dry milk may be declared as "skim milk".

(4) Cheese whey, concentrated cheese whey, and dried cheese whey may be declared as "whey".

(5) If the cheese ingredient contains cheddar cheese, washed cheese, colby cheese, granular cheese, or any mixture of two or more of these, such cheese or such mixture may be designated as "American cheese".

§ 133.125 Cold-pack cheese food with fruits, vegetables, or meats.

(a) Cold-pack cheese food with fruits, vegetables, or meats or mixtures of these is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for cold-pack cheese food by § 133.124, except that:

(1) Its milk fat content is not less than 22 percent.

(2) It contains one or any mixture of two or more of the following: Any properly prepared fresh, cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(3) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by § 133.113(c) is not applicable.

(b) The name of a cold-pack cheese food with fruits, vegetables or meats is "Cold-pack cheese food with _____", the blank being filled in with the common or usual name or names of the fruits, vegetables, or meats used, in order of predominance by weight.

§ 133.127 Cook cheese, koch kaese.

(a) Cook cheese, koch kaese, is the food prepared from skim milk and other ingredients specified in this section by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 80 percent moisture as determined by the method therefor prescribed in § 133.113(c). When tested for phosphatase by the method prescribed in § 133.113(f), 0.25 gram of cook cheese shows a phenol equivalent of not more than 3 micrograms.

(b) Skim milk, or the optional dairy ingredients specified in paragraph (c) of this section, which may be pasteurized, and which may be warmed, are subjected to the action of harmless lactic-acid-producing bacteria, present in such dairy ingredients or added thereto. A culture of a harmless white mold may be added. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the skim milk, may be added to aid in setting the mix to a semisolid mass. The mass is cut, stirred, and heated, with continued stirring, so as to separate the curd and whey. The whey is drained from the curd, and the curd is cured for 2 or 3 days. It is then heated to a temperature of not less than 180° F until the hot curd will drop from a ladle with a consistency like that of honey. The hot cheese is filled into packages and cooled. Pasteurized cream, salt, or caraway seed, or any mixture of two or more of these may be added.

(c) The optional dairy ingredients referred to in paragraph (b) of this section are: Skim milk or concentrated skim milk or nonfat dry milk or a mixture of any two or more of these, with water in a quantity not in excess of that sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(d) For the purposes of this section, "skim milk" means cow's milk from which the milk fat has been separated.

§ 133.128 Cottage cheese.

(a) Cottage cheese is the soft uncured cheese prepared by mixing cottage cheese dry curd with a creaming mixture as provided in paragraph (b) of this section. The milkfat content is not less than 4 percent by weight of the finished food, within limits of good manufacturing practice. The finished food contains not more than 80 percent of moisture, as determined by the method prescribed in § 133.129(a).

(b) The creaming mixture is prepared from safe and suitable ingredients including, but not limited to, milk or substances derived from milk. Any ingredients used that are not derived from milk shall serve a useful function other than building the total solids content of the finished food, and shall be used in a quantity not greater than is reasonably required to accomplish their intended effect. The creaming mixture shall be pasteurized; however, heat labile ingredients, such as bacterial starters, may be added following pasteurization.

(c) The name of the food consists of the following two phrases which shall appear together:

(1) The words "cottage cheese" which shall appear in type of the same size and style.

(2) The statement "not less than ____ percent milkfat" or "____ percent milkfat minimum", the blank being filled in with the whole number that is closest to, but does not exceed, the actual fat content of the product. This statement of fat content shall appear in letters not less than one-half of the height of the letters in the phrase specified in paragraph (c)(1) of this section, but in no case less than one-eighth of an inch in height.

(d) When the optional process described in § 133.129(b)(1)(ii) or (iii) is used to make the cottage cheese dry curd used in cottage cheese, the label shall bear the statement "Directly set" or "Curd set by direct acidification". Wherever the name of the food appears on the label so conspicuously as to be seen under customary conditions of purchase, the statement specified in this paragraph, showing the optional process used, shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter.

(e) The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that:

(1) Concentrated milk, dried milk, and reconstituted milk prepared by addition of water to concentrated milk or dried milk may be declared as "milk".

(2) Concentrated skim milk, nonfat dry milk, and reconstituted skim milk prepared by addition of water to concentrated skim milk or nonfat dry milk may be declared as "skim milk".

(3) Bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, e.g., "made from cultured skim milk".

(4) Milk-clotting enzymes may be declared by the word "enzymes".

§ 133.129 Dry curd cottage cheese.

(a) Cottage cheese dry curd is the soft uncured cheese prepared by the procedure set forth in paragraph (b) of this section. The finished food contains less than 0.5 percent milkfat. It contains not more than 80 percent of moisture, as determined by the method prescribed under "Moisture—Official," on page 272 of "Official Methods of Analysis of the Association of Official Analytical Chemists," Eleventh Edition (1970).[2]

(b)(1) One or more of the dairy ingredients specified in paragraph (b)(2) of this section is pasteurized; calcium chloride may be added in a quantity of not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the mix; thereafter one of the following methods is employed:

(i) Harmless lactic-acid-producing bacteria, with or without rennet and/or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, are added and it is held until it becomes coagulated. The coagulated mass may be cut; it may be warmed; it may be stirred; it is then drained. The curd may be washed with water and further drained; it may be pressed, chilled, worked, seasoned with salt; or

(ii) Food grade phosphoric acid, lactic acid, citric acid, or hydrochloric acid, with or without rennet and/or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, is added in such amount as to reach a pH of between 4.5 and 4.7; coagulation to a firm curd is achieved while heating to a maximum of 120° F without agitation during a continuous process. The coagulated mass may be cut; it may be warmed; it may be stirred; it is then drained. The curd is washed with water, stirred, and further drained. It may be pressed, chilled, worked, seasoned with salt.

(iii) Food grade acids as provided in paragraph (b)(1)(ii) of this section,

D-Glucono-delta-lactone with or without rennet, and/or other safe and suitable milk clotting enzyme that produces equivalent curd formation, are added in such amounts as to reach a final pH value in the range of 4.5–4.8, and it is held until it becomes coagulated. The coagulated mass may be cut; it may be warmed; it may be stirred; it is then drained. The curd is then washed with water, and further drained. It may be pressed, chilled, worked, and seasoned with salt.

(2) The dairy ingredients referred to in paragraph (b)(1) of this section are sweet skim milk, concentrated skim milk, and nonfat dry milk. If concentrated skim milk or nonfat dry milk is used, water may be added in a quantity not in excess of that removed when the skim milk was concentrated or dried.

(3) For the purposes of this section the term "skim milk" means the milk of cows from which the milk fat has been separated, and "concentrated skim milk" means skim milk from which a portion of the water has been removed by evaporation.

(c) The name of the food consists of the following two phrases which shall appear together:

(1) The words "cottage cheese dry curd" or alternatively "dry curd cottage cheese" which shall all appear in type of the same size and style.

(2) The words "less than ½% milkfat" which shall all appear in letters not less than one-half of the height of the letters in the phrase specified in paragraph (c)(1) of this section, but in no case less than one-eighth of an inch in height.

(d) When either of the optional processes described in paragraph (b)(1)(ii) or (iii) of this section is used to make cottage cheese dry curd, the label shall bear the statement "Directly set" or "Curd set by direct acidification". Wherever the name of the food appears on the label so conspicuously as to be seen under customary conditions of purchase, the statement specified in this paragraph, showing the optional process used, shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter.

(e) The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that:

(1) Concentrated skim milk, nonfat dry milk, and reconstituted skim milk prepared by addition of water to concentrated skim milk or nonfat dry milk may be declared as "skim milk".

(2) Bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, e.g., "made from cultured skim milk".

(3) Milk-clotting enzymes may be decleared by the word "enzymes".

§ 133.131 Lowfat cottage cheese.

Lowfat cottage cheese is the food prepared from the same ingredients and in the same manner prescribed in § 133.128 for cottage cheese and complies with all the provisions of § 133.128 (including requirements for the label statement of optional ingredients), except that:

(a) Its content of milkfat is not less than 0.5 percent and not more than 2 percent by weight, within limits of good manufacturing practice.

(b) Its moisture content is not more than 82.5 percent.

(c) The name of the food consists of the following two phrases which shall appear together:

(1) The words "lowfat cottage cheese" which shall appear in type of the same size and style.

(2) The words "_____ % milkfat", the blank being filled in with the fraction "½" or multiple thereof closest to the actual fat content of the product. This statement of fat content shall appear in letters not less than one-half of the height of the letters in the phrase specified in paragraph (c)(1) of this section, but in no case less than one-eighth of an inch in height.

§ 133.133 Cream cheese.

(a) Cream cheese is the soft uncured cheese prepared by the procedure set forth in paragraph (b) of this section. The finished cream cheese contains not less than 33 percent of milk fat and not more than 55 percent of moisture, as determined, respectively by the methods prescribed under "Fat—Official" on page 302 and under "Moisture—Official" on page 301 of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fifth Edition, 1940. (These methods appear in the 10th edition, 1965, p. 248, sec. 15.164; p. 247, sec. 15.157, respectively.)

(b)(1) One or a mixture of two or more of the dairy ingredients specified in paragraph (b)(3) of this section is pasteurized and may be homogenized. To such ingredient or mixture harmless lactic-acid-producing bacteria, with or without rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, are added and it is held until it becomes coagulated. The coagulated mass may be warmed; it may be stirred; it is then drained. The moisture content may be adjusted with cheese whey, concentrated cheese whey, dried cheese whey, or reconstituted cheese whey prepared by addition of water to concentrated cheese whey or dried cheese whey. The curd may be pressed, chilled, worked, seasoned with salt; it may be heated, with or without addition of one or more of the dairy ingredients specified in paragraph (b)(3) of this section, until it becomes fluid, and it may then be homogenized or otherwise mixed.

(2)(i) In the preparation of cream cheese, one or any mixture of two or more of the optional ingredients gum karaya, gum tragacanth, carob bean gum, guar gum, carrageenan, gelatin, algin (sodium alginate), propylene glycol alginate, or xanthan gum may be used; but the quantity of any such ingredient or mixture is such that the total weight of solids contained therein is not more than 0.5 percent by weight of the finished cream cheese.

(ii) When one or more of the optional ingredients in paragraph (b)(2)(i) of this section are used, dioctyl sodium sulfosuccinate complying with the requirements of § 172.810 of this chapter may be used in a quantity not in excess of 0.5 percent by weight of such ingredients.

(3) The dairy ingredients referred to in paragraph (b)(1) of this section are cream, plastic cream, milk, skim milk, concentrated milk, concentrated skim milk, and nonfat dry milk. If concentrated milk, concentrated skim milk, or nonfat dry milk is used, water may be added in a quantity not in excess of that removed when the milk or skim milk was concentrated or dried.

(4) For the purposes of this section, the term "milk" means sweet milk of cows, "skim milk" means milk from which the milk fat has been separated, and "concentrated skim milk" means skim milk from which a portion of the water has been removed by evaporation.

(c) When used in the food, salt, bacterial culture, and enzymes as provided for in paragraph (b)(1) of this section and each of the ingredients listed in paragraph (b)(2) and (3) of this section shall be declared by common name on the label as required by the applicable sections of Part 101 of this chapter except that:

(1) Any cream as defined in Part 131 of this chapter and plastic cream may be declared as "cream".

(2) Concentrated milk and reconstituted milk prepared by addition of water to concentrated milk may be declared as "milk".

(3) Concentrated skim milk, nonfat dry milk, and reconstituted skim milk prepared by addition of water to concentrated skim milk or nonfat dry milk may be declared as "skim milk".

(4) Bacterial cultures may be declared as "cheese culture" or by the word "cultured" followed by the name of the substrate, e.g., "made from cultured cream".

(5) Milk clotting enzymes may be declared by the word "enzymes".

§ 133.134 Cream cheese with other foods.

(a) Cream cheese with other foods is the class of foods each of which is prepared by mixing, with or without the aid of heat, cream cheese with one or a mixture of two or more properly prepared foods (except other cheeses), such as fresh, cooked, canned, or dried fruits or vegetables; cooked or canned meats; relishes, pickles, or other foods suitable for blending with cream cheese. The amount of the added food or foods must be sufficient to so differentiate the mixture that it does not simulate cream cheese. The mixture may also contain:

(1)(i) One or any mixture of two or more of the following optional ingredients: Gum karaya, gum tragacanth, carob bean gum, gelatin, guar gum, sodium carboxymethylcellulose (cellulose gum), carrageenan, oat gum, algin (sodium alginate), propylene glycol alginate, or xanthan gum. The total quantity of any such substances, including that contained in the cream cheese, is

not more than 0.8 percent by weight of the finished food.

(ii) When one or more of the optional ingredients in paragraph (a)(1)(i) of this section are used, dioctyl sodium sulfosuccinate complying with the requirements of § 172.810 of this chapter may be used in a quantity not in excess of 0.5 percent by weight of such ingredients.

(2) Artificial coloring, unless such addition conceals damage or inferiority or makes the finished food appear better or of greater value than it is.

(b) No water other than that contained in the added food ingredients is used, but the moisture content of the mixture in no case is more than 60 percent. The milk fat is not less than 33 percent of the percent by weight of the cream cheese used, but in no case is it less than 27 percent of the finished food. Moisture and fat are determined by the methods prescribed in § 133.113(c), except that when the added food contains fat the method prescribed for the determination of fat is not applicable.

(c) The name of the food is "cream cheese with _____" or "cream cheese and _____", the blank being filled in with the common names of the foods added, in order of predominance by weight. The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. Wherever any word or statement emphasizing the name of an ingredient appears on the label (other than in an ingredient statement as specified in paragraph (d) of this section) so conspicuously as to be easily seen under customary conditions of purchase, the full name of the food shall immediately and conspicuously precede or follow such word or statement in type of at least the same size as the type used in such word or statement.

(d) The common name of each of the ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 133.136 Washed curd and soaked curd cheese.

(a) Washed curd cheese, soaked curd cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 42 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 133.113(c). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the milk, is added to set the milk to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. The whey is drained off, and the curd is matted into a cohesive mass. The mass is cut into slabs, which are so piled and handled as to promote the drainage of whey and the development of acidity. The slabs are then cut into pieces, cooled in water, and soaked therein until the whey is partly extracted and water is absorbed. The curd is drained, salted, stirred, and pressed into forms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of washed curd cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F for a period of not less than 30 minutes or for a time and at a temperature equivalent thereto in phosphatase destruction. Washed curd cheese shall be deemed not to have been made from pasteurized milk if 0.25 gram. shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 133.113(f).

(3) During the cheese-making process the milk may be treated as provided in § 133.113(e)(3).

(d) Washed curd cheese in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e)(1) If washed curd cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(2) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in this section, showing the optional ingredient used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 133.137 Washed curd cheese for manufacturing.

Washed curd cheese for manufacturing conforms to the definition and standard of identity prescribed for washed curd cheese by § 133.136, except that the milk is not pasteurized, curing is not required, and the provisions of paragraph (d) of that section do not apply.

§ 133.138 Edam cheese.

(a) Edam cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 45 percent of moisture, and its solids contain not less than 40 percent of milk fat, as determined by the methods prescribed in § 133.113(c). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F for not less than 60 days. Edam cheese is made in ball or loaf shapes, and the surface is covered with a paraffin or other tightly adhering coating. The covering or coating may be natural in color or may be colored red or any other color.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the milk, is added to set the milk to a semisolid mass. After coagulation the mass is cut into small cube-shaped pieces with sides approximately ⅜-inch long. The mass is stirred and heated to about 90° F, and so handled by further stirring, heating, dilution with water or salt brine, and salting as to promote and regulate the separation of curd and whey. When the desired curd is obtained, it is transferred to forms permitting drainage of whey. During drainage the curd is pressed and turned. After drainage the curd is removed from the forms and is salted and cured. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of edam cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk, water in a quan-

tity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Edam cheese shall be deemed not to have been made from pasteurized milk if 0.25 gram shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 133.113(f).

(d) Edam cheese in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, soduim sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e)(1) If edam cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a perservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(2) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in this section, showing the optional ingredient used, shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter.

§ 133.140 Gammelost cheese.

(a) Gammelost cheese is the food prepared from the skim milk of cows and the other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. It contains not more than 52 percent of moisture, as determined by the method prescribed in § 133.113(c).

(b) Skim milk, which may be pasteurized, is subjected to the action of harmless lactic-acid-producing bacteria, present in such skim milk or added thereto. The development of acidity is continued until the skim milk coagulates to a semisolid mass. The mass is stirred and heated until a temperature of about 145° F is reached, and is held at that temperature for not less than ½ hour. The whey is drained off and the curd removed and placed in forms and pressed. The shaped curd is placed in whey and heated for 3 or 4 hours. It is then removed from the whey and may again be pressed. It is then stored under conditions suitable for curing.

§ 133.141 Gorgonzola cheese.

(a) Gorgonzola cheese is the food prepared from cow's milk or goat's milk or mixtures of these, and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It is characterized by the presence of bluish-green mold throughout the cheese. It is made in loaves weighing between 14 and 17 pounds. It contains not more than 42 percent moisture, and its solids contain not less than 50 percent milk fat, as determined by the methods prescribed in § 133.113(c). It is not less than 90 days old

(b) Milk, which may be pasteurized or clarified or both, which may be warmed, and which may be homogenized, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial green or blue coloring in a quantity which neutralizes any natural yellow coloring in the curd may be added. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the milk, is added to set the milk to a semisolid mass. The mass is cut into smaller portions and allowed to stand for a time. The mixed curd and whey is placed into forms permitting further drainage. While being placed in forms, spores, of the mold *Penicillium roquefortii* are added. The forms are turned several times during drainage. When sufficiently drained, the shaped curd is removed from the forms and salted with dry salt or brine. Perforations are then made in the shaped curd and it is held at a temperature of approximately 50° F, at 90 to 95 percent relative humidity, until the characteristic mold growth has developed. During storage the surface of the cheese is scraped, if necessary, to remove surface growth of undesirable microorganisms. The rind of the cheese may be coated with a vegetable food fat or oil (which may be hydrogenated), or any combination of two or more such articles. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of gorgonzola cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk or goat's milk or mixtures of these.

(2) Such milk may be bleached by the use of benzoyl peroxide or mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate, but the weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk being bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, vitamin A is added to the curd in such quantity as to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(3) Such milk may be adjusted by separating part of the fat therefrom or by adding one or more of the following: (In the case of cow's milk) cream, cream which has been treated in the manner provided in paragraph (c)(2) of this section, concentrated skim milk, nonfat dry milk; (in the case of goat's milk) the corresponding products obtained from goat's milk; water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(d) The food may have applied to its surface an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e) (1) If the milk used is bleached, the label shall bear the statement "milk bleached with benzoyl peroxide".

(2) If the food contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement "_____ added to retard surface mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(3) Whenever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed in this paragraph showing the optional ingredients used shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter.

§ 133.142 Gouda cheese.

Gouda cheese conforms to the definition and standard of identity and complies with the requirements for label declaration of optional ingredients prescribed for edam cheese by § 133.138, except that the fat content of its solids is not less than 46 percent. It is made in the shape of a compressed sphere, in which the compressed sides are parallel and flat. The surface may or may not be covered with red-colored paraffin or similar tightly adhering coating.

§ 133.144 Granular and stirred curd cheese.

(a) Granular cheese, stirred curd cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 39 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 133.113(c). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be

warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the milk, is added to set the milk to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. A part of the whey is drained off. The curd is then alternately stirred and drained to prevent matting and to remove whey from curd. The curd is then salted, stirred, drained, and pressed into forms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of granular cheese, may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F for a period of not less than 30 minutes or for a time and at a temperature equivalent thereto in phosphatase destruction. Granular cheese shall be deemed not to have been made from pasteurized milk of 0.25 gram shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 133.113(f).

(3) During the cheese-making process the milk may be treated as provided in § 133.113(e)(3).

(d) Granular cheese in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e)(1) If granular cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(2) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in this section, showing the optional ingredient used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 133.145 Granular cheese for manufacturing.

Granular cheese for manufacturing conforms to the definition and standard of identity prescribed for granular cheese by § 133.144, except that the milk is not pasteurized, curing is not required, and the provisions of paragraph (d) of that section do not apply.

§ 133.146 Grated cheeses.

(a)(1) Grated cheeses are the class of food prepared by grinding, grating, shredding, or otherwise comminuting cheese of one variety or a mixture of two or more varieties. The cheese varieties that may be used are those for which definitions and standards of identity have been promulgated pursuant to section 401 of the act, except cream cheese, neufchatel cheese, cottage cheese, creamed cottage cheese, cook cheese, and skim milk cheese for manufacturing. One or more of the optional ingredients specified in paragraph (b) of this section may be used.

(2) Any cheese ingredient used is made from pasteurized milk or is held at a temperature of not less than 35° F for not less than 60 days.

(3) Each cheese ingredient used must be present at a level of not less than 2 percent by weight of the finished food.

(4) In the manufacture of the finished food, moisture may be removed from the cheese ingredients but no moisture is added, except as provided for in paragraph (b)(1) of this section.

(5)(i) The fat content of the solids of grated cheese made from a single variety of cheese is not more than 1 below the minimum percentage prescribed by the definition and standard of identity for the variety of cheese used.

(ii) The fat content of the solids of grated cheeses made from two or more varieties of cheese is not more than 1 below the arithmetical average of the minimum fat content percentages prescribed by the definitions and standards of identity for the varieties of cheese used, but in no case is the fat content less than 31 percent.

(6) Moisture and fat in grated cheeses are determined by the methods prescribed in § 133.113(c).

(b) The optional ingredients referred to in paragraph (a) of this section are:

(1) A mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these in an amount not to exceed 0.3 percent by weight of the finished food calculated as sorbic acid. The salts of sorbic acid provided for herein may be applied in aqueous solution, the amount of water used being not more than that required for application of these water-soluble salts in accordance with good commercial practice.

(2) An anticaking agent consisting of silicon dioxide (complying with the provisions of § 172.480 of this chapter), calcium silicate (complying with the provisions of § 172.410 of this chapter), sodium silicoaluminate, microcrystalline cellulose, or any combination of two or more of these in an amount not to exceed 2 percent by weight of the finished food.

(3) Spices.

(4) Safe and suitable flavoring substances other than any which singly or in combination with other ingredients simulate the flavor of cheese of any age or variety.

(c)(1) The name of the food, if it is made with only one variety of cheese, is "grated _____ cheese", the blank being filled in with the name of the variety used.

(2) The name of the food, if the only cheese ingredients used are parmesan and romano cheese, each being present at a level of not less than 25 percent by weight of the finished food, is "grated _____ and _____ cheese", the blanks being filled in with the names "parmesan" and "romano" in order of predominance by weight. The varietal designation "reggiano" may be used for "parmesan".

(3) The name of the food, if it is made with a mixture of cheese varieties (not including parmesan or romano cheese) with each of the varieties used being present at a level of not less than 25 percent of the weight of the finished food, is "grated _____ cheese", the blank being filled in with the names of the two or more varieties in order of predominance by weight.

(4) The name of the food, if it is made with a mixture of cheese varieties in which one or more varieties (not including parmesan or romano cheese) are each present at a level of not less than 25 percent by weight of the finished food, and one or more other varieties (which may include parmesan and romano cheese) are each present at a level of not less than 2 percent but in the aggregate not more than 10 percent, is "grated _____ cheese with other grated cheese" or "grated _____ cheese with other grated cheeses", as appropriate, the blank being filled in with the name or names of those cheese varieties present at levels of not less than 25 percent by weight of the finished food in order of predominance, in letters not more than twice as high as the letters in the phrase "with other grated cheese(s)".

(5) The name of the food, if it is made with a mixture of cheese varieties other than those specified by paragraphs (c)(2), (3), and (4) of this section is "grated cheeses".

(6) The cheese variety names prescribed for use in the name of the food by paragraphs (c)(1), (2), (3), and (4) of this section are those specified by applicable standard of identity sections of this part, except that the variety name "American cheese" may be used for cheddar, washed curd, colby, or granular cheese. Any mixture of two or more of these varieties may, for the purposes of this section, be considered as a single variety with the name "American cheese".

(7) If the particles of cheese are in the form of cylinders, shreds, or strings,

the word "shredded", or if they are in the form of chips, the word "chipped" or "chopped", may be used in lieu of the word "grated" in the specified name of the product.

(d)(1) If the food contains an optional mold-inhibiting ingredient as specified in paragraph (b)(1) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredients used.

(2) If it contains an optional anticaking agent as specified in paragraph (b)(2) of this section, the label shall bear the statement "_____ added to prevent caking", the blank being filled in with the common name or names of the anticaking agents used.

(3) If it contains a spice as specified in paragraph (b)(3) of this section, the label shall bear the statement "spice added", "with added spice", or "spiced with _____", the blank being filled in with the common or usual name of the spice used.

(4) If it contains a flavoring substance as specified in paragraph (b)(4) of this section, the label shall bear the statement "flavoring added", "with added flavoring", or "flavored with _____", the blank being filled in with the common or usual name of the flavoring used. If the flavoring used is artificial, the word "artificially" shall precede the statement "flavored with _____".

(5) If the name of one or more varieties of cheese used in grated cheeses does not appear as a part of the name of the food, the names of all cheese varieties used shall be listed in order of predominance by weight.

(e) The words and statements specified in paragraph (d) of this section showing the optional ingredients present shall be listed on the principal display panel or panels or any appropriate information panel without obscuring design, vignettes, or crowding. The declaration shall appear in conspicuous and easily legible letters of boldface print or type the size of which shall be not less than one-half of that required by Part 101 of this chapter for the statement of net quantity of contents appearing on the label, but in no case less than one-sixteenth of an inch in height. The entire declaration shall appear on at least one panel of the label and in lines generally parallel to the base on which the container rests as it is designed to be displayed.

§ 133.147 Grated American cheese food.

(a)(1) Grated American cheese food is the food prepared by mixing, with or without the aid of heat, one or more of the optional cheese ingredients prescribed in paragraph (b) of this section with one or more of the optional ingredients prescribed in paragraph (c) of this section, into a uniformly blended, partially dehydrated, powdered or granular mixture.

(2) Grated American cheese food contains not less than 23 percent of milk fat, as determined by the methods prescribed in § 133.113(c).

(b) The optional cheese ingredients referred to in paragraph (a) of this section are cheddar cheese, washed curd cheese, colby cheese, and granular cheese.

(c) The other optional ingredients referred to in paragraph (a) of this section are:

(1) Nonfat dry milk.

(2) Dried whey.

(3) An emulsifying agent consisting of one or any mixture of two or more of the emulsifying ingredients named in § 133.173(e)(1), in such quantity that the weight of the solids thereof is not more than 3 percent of the weight of the grated American cheese food.

(4) An acidifying agent consisting of one or more of the acid-reacting ingredients named in § 133.173(e)(2).

(5) Salt.

(6) Artificial coloring.

(d) The name of the food is "Grated American cheese food". The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. Wherever any word or statement emphasizing the name of any ingredient appears on the label (other than in an ingredient statement as specified in paragraph (e) of this section) so conspicuously as to be easily seen under customary conditions of purchase, the full name of the food shall immediately and conspicuously precede or follow such word or statement in type of at least the same size as the type used in such word or statement.

(e) The common name of each of the ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these may be designated "American cheese".

§ 133.148 Hard grating cheeses.

(a) The cheeses for which definitions and standards of identity are prescribed by this section are hard grating cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from milk and the other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. They contain not more than 34 percent of moisture, and their solids contain not less than 32 percent of milk fat, as determined by the methods prescribed in § 133.113(c). Hard grating cheeses are cured for not less than 6 months.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-producing bacteria, present in such milk or added thereto. Sufficient rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. The mass is cut into small particles, stirred, and heated. The curd is separated from the whey, drained, shaped into forms, pressed, salted, and cured. The rind may be colored or rubbed with vegetable oil or both. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of hard grating cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section, the word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any such concentrated or dried products used.

(d) Hard grating cheeses in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e) The name of each hard grating cheese for which a definition and standard of identity is prescribed by this section is "Hard grating cheese", preceded or followed by:

(1) The specific common or usual name of such hard grating cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name that is not false or misleading in any particular.

(f)(1) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement "made from _____", the blank being filled in with the name or names of the milk used, in order of predominance by weight.

(2) If hard grating cheeses in sliced or cut form contain an optional mold-inhibiting ingredient as provided for in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary condi-

tions of purchase, the words and statements prescribed by this section, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 133.149 Gruyere cheese.

(a) Gruyere cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 39 percent of moisture and its solids contain not less than 45 percent of milk fat, as determined by the methods prescribed in § 133.113 (c). It contains small holes, or eyes. It has a mild flavor, due in part to the growth of surface-curing agents. It is not less than 90 days old.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto; harmless propionic-acid-producing bacteria may also be added. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the milk, is added to set the milk to a semisolid mass. The mass is cut into particles similar in size to wheat kernels. For about 30 minutes the particles are alternately stirred and allowed to settle. The temperature is raised to about 126° F. Stirring is continued until the curd becomes firm. The curd is transferred to hoops or forms, and pressed until the desired shape and firmness are obtained. The cheese is surface-salted while held at a temperature of 48° F to 54° F for a few days. It is soaked for 1 day in a saturated salt solution. It is then held for 3 weeks in a salting cellar and wiped every 2 days with brine cloth to ensure growth of biological curing agents on the rind. It is then removed to a heating room and held at progressively higher temperatures, finally reaching 65° F with a relative humidity of 85 to 90 percent, for several weeks, during which time small holes, or so-called eyes, form. The cheese is then stored at a lower temperature for further curing. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of gruyere cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section, the word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto cream or skim milk.

(d) Gruyere cheese in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e) (1) If gruyere cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(2) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in this section, showing the optional ingredient used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 133.150 Hard cheeses.

(a) The cheeses for which definitions and standards of identity are prescribed by this section are hard cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from milk and the other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. They contain not more than 39 percent of moisture, and their solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 133.113(c). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, with or without other harmless flavor-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is cut into small particles, stirred, and heated. The curd is separated from the whey, drained, and shaped into forms, and may be pressed. The curd is salted at some stage of the manufacturing process. The shaped curd may be cured. The rind may be coated with paraffin or rubbed with vegetable oil. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of hard cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used. Harmless flavor-producing microorganisms may be added, and curing may be conducted under suitable conditions for the development of biological curing agents.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom, or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any concentrated or dried products used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. A hard cheese shall be deemed not to have been made from pasteurized milk if 0.25 gram shows a phenol equivalent of more than 3 micrograms, when tested by the method prescribed in § 133.113(f).

(d) Hard cheeses in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e) The name of each hard cheese for which a definition and standard of identity is prescribed by this section is "Hard cheese", preceded or followed by:

(1) The specific common or unusual name of such hard cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized, therefor, an arbitrary or fanciful name that is not false or misleading in any particular.

(f) (1) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement "made from _____", the blank being filled in with the name or names of the milk used, in order of predominance by weight.

(2) If hard cheeses in sliced or cut form contain an optional mold-inhibiting ingredient as provided for in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed by this section, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 133.152 Limburger cheese.

(a) Limburger cheese is the food prepared from milk and other ingredients

specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 50 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 133.113(c). If the milk used is not pasteurized, limburger cheese is held at a temperature of not less than 35° F for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, is brought to a temperature of about 92° F and subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the milk, is added to set the milk to a semisolid mass. The mass is cut into cubes with sides approximately ½-inch long. After a few minutes the mass is stirred and heated, gradually raising the temperature to 96° F to 98° F. The curd is then allowed to settle, most of the whey is drained off, and the remaining curd and whey dipped into molds. During drainage the curd may be pressed. It is turned at regular intervals. After drainage the curd is cut into pieces of desired size and dry-salted at intervals for 24 to 48 hours. The cheese is then cured with frequent applications of a weak brine solution to the surface, until the proper growth of surface-curing organisms is obtained. It is then wrapped and held in storage for development of as much additional flavor as is desired. When made from pasteurized milk, the milk is brought to a temperature of 89° F to 90° F after pasteurization. A culture of harmless lactic-acid-producing bacteria is added. Calcium chloride may be added, as to raw milk. The procedure then is the same as with raw milk, except that heating is to 94° F. After most of the whey is drained off, salt brine at a temperature of 66° F to 70° F is added, so that the pH of the curd is about 4.8. The mixed curd, whey, and brine is dipped into molds and the same procedure followed as when raw milk is used. Whether pasteurized or unpasteurized milk is used, a harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of limburger cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction.

§ 133.153 Monterey cheese and monterey jack cheese.

(a) Monterey cheese, monterey jack cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 44 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 133.113(c).

(b) Milk, which is pasteurized, and which may be clarified, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the milk, is added to set the milk to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. Part of the whey is drained off, and water or salt brine may be added. The curd is drained and placed in a muslin or sheeting cloth, formed into a ball and pressed; or the curd is placed in a cheese hoop and pressed. Later, the cloth bandage is removed, and the cheese may be covered with paraffin or dipped in vegetable oil, and may have rice flour sprinkled on the surface. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of monterey cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Monterey cheese shall be deemed not to have been made from pasteurized milk if 0.25 gram shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 133.113(f).

(d) Monterey cheese in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e) (1) If monterey cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(2) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in this section, showing the optional ingredient used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 133.154 High-moisture jack cheese.

High-moisture jack cheese conforms to the definition and standard of identity and is subject to the requirement for label statement of optional ingredients prescribed for monterey cheese by § 133.153, except that its moisture content is more than 44 percent but less than 50 percent.

§ 133.155 Mozzarella cheese and scamorza cheese.

(a) Mozzarella cheese, scamorza cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. It may be molded into various shapes. It contains more than 52 percent but not more than 60 percent of moisture, and its milk fat content, calculated on the solids basis, is not less than 45 percent, as determined by the methods prescribed in § 133.113(c).

(b) Milk, which is pasteurized, is warmed to approximately 88° F and subjected to the action of harmless lactic-acid-producing bacteria, which may be added thereto as starter. The milk may be acidified with vinegar. Liquid rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both may be added to aid in setting the milk to a semisolid mass. The mass is cut, and it may be stirred to facilitate separation of whey from the curd. The whey is drained and the curd may be washed with cold water and the water drained off. The curd may be collected in bundles for further drainage and for ripening. The curd may be iced, it may be held under refrigeration, and it may be permitted to warm to room temperature and ripen further. The curd may be cut. It is immersed in hot water or heated with steam and is kneaded and stretched until smooth and free of lumps.

Then it is cut and molded. The molded curd is firmed by immersion in cold water and may be salted in brine and drained.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding cream or skim milk or both.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 145° F for a period of not less than 30 minutes, or for a time and temperature equivalent thereto in phosphatase destruction. The finished food shall be deemed not to have been made from pasteurized milk if 0.25 gram shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 133.113(f), provolone modification.

§ 133.156 Low-moisture mozzarella and scamorza cheese.

(a) Low moisture mozzarella cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It may be molded into various shapes. Its moisture content is more than 45 percent but not more than 52 percent, and its milk fat content, calculated on the solids basis, is not less than 45 percent, as determined by the method prescribed in § 133.113(c).

(b) Milk, which is pasteurized, and which may be clarified or homogenized or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, which may be added thereto as starter. The milk may be acidified with vinegar. Rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to aid in setting the milk to a semisolid mass. The mass is cut, stirred, and allowed to stand. It may be reheated and again stirred. The whey is drained, and the curd may be cut and piled to promote further separation of whey. It may be washed with cold water and the water drained off. The curd may be collected in bundles for further drainage and ripening. The curd may be iced, it may be held under refrigeration, and it may be permitted to warm to room temperature and ripen further. The curd may be cut. It is immersed in hot water or heated with steam and is kneaded and stretched until smooth and free of lumps. Then it is cut and molded. In molding, the curd is kept sufficiently warm to cause proper sealing of the surface. The molded curd is firmed by immersion in cold water and may be salted in brine and drained.

(c) For the purposes of this section:

(1) The word "milk" mean cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk, and water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 145° F for a period of 30 minutes or for a time and temperature equivalent thereto in phosphatase destruction. The finished food shall be deemed not to have been made from pasteurized milk if 0.25 gram shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 133.113(f), provolone modification.

(d) Low moisture mozzarella cheese, low moisture scamorza cheese in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e) (1) If low moisture mozzarella cheese, low moisture scamorza cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(2) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed by this section, showing the optional ingredient (or ingredients) used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 133.157 Part-skim mozzarella and scamorza cheese.

Part-skim mozzarella cheese, part-skim scamorza cheese conforms to the definition and standard of identity as prescribed for mozzarella cheese by § 133.155, except that its milk fat content, calculated on the solids basis, is less than 45 percent but not less than 30 percent.

§ 133.158 Low-moisture part-skim mozzarella and scamorza cheese.

Low moisture part-skim mozzarella cheese, low moisture part-skim scamorza cheese conforms to the definition and standard of identity and complies with the requirements for label declaration of optional ingredients prescribed for low moisture mozzarella cheese, low moisture scamorza cheese by § 133.156; except that its milk fat content, calculated on the solids basis, is less than 45 percent but not less than 30 percent.

§ 133.160 Muenster and munster cheese.

(a) Muenster cheese, munster cheese, is the food prepared from pasteurized milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 46 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 133.113(c).

(b) Milk, which is pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the milk, is added to set the milk to a semisolid mass. After coagulation the mass is divided into small portions, stirred, and heated, with or without dilution with water or salt brine, so as to promote and regulate the separation of whey and curd. The curd is transferred to forms permitting drainage of the whey. During drainage the curd may be pressed and turned. After drainage the curd is removed from the forms and is salted. The surface of the cheese may be rubbed with vegetable oil. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of muenster cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Muenster cheese shall be deemed not to have been made from pasteurized milk if 0.25 gram shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 133.113(f).

(d) Muenster cheese in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in

an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e) (1) If muenster cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(2) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in this section, showing the optional ingredient used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 133.161 Muenster and munster cheese for manufacturing.

Muenster cheese for manufacturing conforms to the definition and standard of identity for muenster cheese prescribed by § 133.160, except that the milk is not pasteurized and the provisions of paragraphs (d) and (e) of that section do not apply.

§ 133.162 Neufchatel cheese.

(a) Neufchatel cheese is the soft uncured cheese prepared by the procedure set forth in paragraph (b) of this section. The finished neufchatel cheese contains not less than 20 percent but less than 33 percent of milk fat and not more than 65 percent of moisture, as determined, respectively, by the methods prescribed under "Fat—Official" on page 302 and under "Moisture—Official" on page 301 of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fifth Edition, 1940. (These methods appear in the 10th edition, 1965, p. 248, sec. 15.164; p. 247, sec. 15.157, respectively.)

(b) (1) One or a mixture of two or more of the dairy ingredients specified in paragraph (b) (3) of this section is pasteurized and may be homogenized. To such ingredient or mixture harmless lactic-acid-producing bacteria, with or without rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, are added and it is held until it becomes coagulated. The coagulated mass may be warmed; it may be stirred; it is then drained. The moisture content may be adjusted with cheese whey, concentrated cheese whey, dried cheese whey, or reconstituted cheese whey prepared by addition of water to concentrated cheese whey or dried cheese whey. The curd may be pressed, chilled, worked, seasoned with salt; it may be heated, with or without addition of one or more of the dairy ingredients specified in paragraph (b) (3) of this section, until it becomes fluid, and it may then be homogenized or otherwise mixed.

(2) (i) In the preparation of neufchatel cheese, one or any mixture of two or more of the optional ingredients gum karaya, gum tragacanth, carob bean gum, guar gum, carrageenan, gelatin, algin (sodium alginate), propylene glycol alginate, or xanthan gum may be used; but the quantity of any such ingredient or mixture is such that the total weight of solids contained therein is not more than 0.5 percent by weight of the finished neufchatel cheese.

(ii) When one or more of the optional ingredients in paragraph (b) (2) (i) of this section are used, dioctyl sodium sulfosuccinate complying with the requirements of § 172.810 of this chapter may be used in a quantity not in excess of 0.5 percent by weight of such ingredients.

(3) The dairy ingredients referred to in paragraph (b) (1) of this section are cream, plastic cream, milk, skim milk, concentrated milk, concentrated skim milk, and nonfat dry milk. If concentrated milk, concentrated skim milk, or nonfat dry milk is used, water may be added in a quantity not in excess of that removed when the milk or skim milk was concentrated or dried.

(4) For the purposes of this section the term "milk" means sweet milk of cows; "skim milk" means milk from which the milk fat has been separated, and "concentrated skim milk" means skim milk from which a portion of the water has been removed by evaporation.

(c) When used in the food, salt, bacterial culture, and enzymes as provided for in paragraph (b) (1) of this section and each of the ingredients listed in paragraph (b) (2) and (3) of this section shall be declared by common name on the label as required by the applicable sections of Part 101 of this chapter except that:

(1) Any cream as defined in Part 131 of this chapter and plastic cream may be declared as "cream".

(2) Concentrated milk and reconstituted milk prepared by addition of water to concentrated milk may be declared as "milk".

(3) Concentrated skim milk, nonfat dry milk, and reconstituted skim milk prepared by addition of water to concentrated skim milk or nonfat dry milk may be declared as "skim milk".

(4) Bacterial cultures may be declared as "cheese culture" or by the word "cultured" followed by the name of the substrate, e.g., "made from cultured cream".

(5) Milk clotting enzymes may be declared by the word "enzymes".

§ 133.164 Nuworld cheese.

(a) Nuworld cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It is characterized by the presence of creamy-white mold throughout the cheese. It contains not more than 46 percent of moisture and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 133.113(c). It is not less than 60 days old.

(b) Milk, which may be pasteurized or clarified or both, which may be warmed, and which may be homogenized, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial green or blue coloring, in a quantity which neutralizes any natural yellow coloring in the curd, may be added. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of milk, is added to set the milk to a semisolid mass. The mass is cut into smaller portions and allowed to stand for a time. The mixed curd and whey is placed in forms permitting further drainage. While being placed in forms, spores of a white mutant of the mold *Penicillium roquefortii* are added. The forms are turned several times during drainage. When sufficiently drained, the shaped curd is removed from the form and salted with dry salt or brine. Perforations are then made in the shaped curd, and it is held at a temperature of approximately 50° F, at 90 percent to 95 percent relative humidity, until the characteristic mold growth has developed. During storage, the surface of the cheese may be scraped to remove surface growth of undesirable microorganisms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of nuworld cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section, the word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, concentrated skim milk, nonfat dry milk, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

§ 133.165 Parmesan and reggiano cheese.

(a) Parmesan cheese, reggiano cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It is characterized by a granular texture and a hard and brittle rind. It grates readily. It contains not more than 32 percent of moisture, and its solids contain not less than 32 percent of milk fat, as determined by the methods prescribed in § 133.113(c). It is cured for not less than 10 months.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces

equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the milk, is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. The mass is cut into pieces no larger than wheat kernels, heated, and stirred until the temperature reaches between 115° F and 125° F. The curd is allowed to settle and is then removed from the kettle or vat, drained for a short time, placed in hoops, and pressed. The pressed curd is removed and salted in brine, or dry-salted. The cheese is cured in a cool, ventilated room. The rind of the cheese may be coated or colored. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of parmesan cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) (1) For the purposes of this section, the word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(2) Such milk may be bleached by the use of benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate; but the weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, sufficient vitamin A is added to the curd to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(d) Parmesan cheese in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e) (1) If the milk used is bleached, the label shall bear the statement "Milk bleached with benzoyl peroxide."

(2) If parmesan cheese in sliced or cut form contains an optional mold-inhibiting ingredient as provided for in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed by this section, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 133.167 Pasteurized blended cheese.

Pasteurized blended cheese conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for pasteurized process cheese by § 133.169, except that:

(a) In mixtures of two or more cheeses, cream cheese or neufchatel cheese may be used.

(b) None of the ingredients prescribed or permitted for pasteurized process cheese by § 133.169 (c) and (d) (1) is used.

(c) In case of mixtures of two or more cheeses containing cream cheese or neufchatel cheese, the moisture content is not more than the arithmetical average of the maximum moisture contents prescribed by the definitions and standards of identity for the varieties of cheeses blended, for which such limits have been prescribed.

(d) The word "process" is replaced by the word "blended" in the name prescribed by § 133.169(e).

§ 133.168 Pasteurized blended cheese with fruits, vegetables, or meats.

(a) Pasteurized blended cheese with fruits, vegetables, or meats or mixtures of these is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for pasteurized blended cheese by § 133.167, except that:

(1) Its moisture content may be 1 percent more, and the milk fat content of its solids may be 1 percent less, than the limits prescribed by § 133.167 for moisture and milk fat in the corresponding pasteurized blended cheese.

(2) It contains one or any mixture of two or more of the following: Any properly prepared cooked, canned, or dried fruit; any properly prepared cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(3) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by § 133.113(c) is not applicable.

(b) The name of a pasteurized blended cheese with fruits, vegetables, or meats is the name prescribed by § 133.167 for the applicable pasteurized blended cheese, followed by the term "with _____", the blank being filled in with the common or usual name or names of the fruits, vegetables, or meats used, in order of predominance by weight.

§ 133.169 Pasteurized process cheese.

(a) (1) Pasteurized process cheese is the food prepared by comminuting and mixing, with the aid of heat, one or more cheeses of the same or two or more varieties, except cream cheese, neufchatel cheese, cottage cheese, lowfat cottage cheese, cottage cheese dry curd, cook cheese, hard grating cheese, semisoft part-skim cheese, part-skim spiced cheese, and skim milk cheese for manufacturing with an emulsifying agent prescribed by paragraph (c) of this section into a homogeneous plastic mass. One or more of the optional ingredients designated in paragraph (d) of this section may be used.

(2) During its preparation, pasteurized process cheese is heated for not less than 30 seconds at a temperature of not less than 150° F. When tested for phosphatase by the method prescribed in § 133.113(f), the phenol equivalent of 0.25 gram of pasteurized process cheese is not more than 3 micrograms.

(3) (i) The moisture content of a pasteurized process cheese made from a single variety of cheese is not more than 1 percent greater than the maximum moisture content prescribed by the definition and standard of identity, if any there be, for the variety of cheese used; but in no case is more than 43 percent, except that the moisture content of pasteurized process washed curd cheese or pasteurized process colby cheese is not more than 40 percent; the moisture content of pasteurized process swiss cheese or pasteurized process gruyere cheese is not more than 44 percent; and the moisture content of pasteurized process limburger cheese is not more than 51 percent.

(ii) The fat content of the solids of a pasteurized process cheese made from a single variety of cheese is not less than the minimum prescribed by the definition and standard of identity, if any there be, for the variety of cheese used, but in no case is less than 47 percent; except that the fat content of the solids of pasteurized process swiss cheese is not less than 43 percent, and the fat content of the solids of pasteurized process gruyere cheese is not less than 45 percent.

(4) (i) The moisture content of a pasteurized process cheese made from two or more varieties of cheese is not more than 1 percent greater than the arithmetical average of the maximum moisture contents prescribed by the definitions and standards of identity, if any there be, for the varieties of cheese used; but in no case is the moisture content more than 43 percent, except that the moisture content of a pasteurized process cheese made from two or more of the varieties cheddar cheese, washed curd cheese, colby cheese, and granular cheese is not more than 40 percent, and the moisture content of a mixture of swiss cheese and gruyere cheese is not more than 44 percent.

(ii) The fat content of the solids of a pasteurized process cheese made from two or more varieties of cheese is not less than the arithmetical average of the minimum fat contents prescribed by the definitions and standards of identity, if any there be, for the varieties of cheese used, but in no case is less than 47 percent, except that the fat content of the solids of a pasteurized process gruyere cheese made from a mixture of swiss cheese and gruyere cheese is not less than 45 percent.

(5) Moisture and fat are determined by the methods prescribed in § 133.113(c).

(6) The weight of each variety of cheese in a pasteurized process cheese made from two varieties of cheese is not less than 25 percent of the total weight of both, except that the weight of blue cheese, nuworld cheese, roquefort cheese, or gorgonzola cheese is not less than 10 percent of the total weight of both, and the weight of limburger cheese is not less than 5 percent of the total weight of both. The weight of each variety of cheese in a pasteurized process cheese made from three or more varieties of cheese is not less than 15 percent of the total weight of all, except that the weight of blue cheese, nuworld cheese, roquefort cheese, or gorgonzola cheese is not less than 5 percent of the total weight of all, and the weight of limburger cheese is not less than 3 percent of the total weight of all. These limits do not apply to the quantity of cheddar cheese, washed curd cheese, colby cheese and granular cheese in mixtures which are designated as "American cheese" as prescribed in paragraph (e)(2)(ii) of this section. Such mixtures are considered as one variety of cheese for the purposes of this paragraph (a)(6).

(7) For the purposes of this section, cheddar cheese for manufacturing, washed curd cheese for manufacturing, colby cheese for manufacturing, granular cheese for manufacturing, brick cheese for manufacturing, muenster cheese for manufacturing, and swiss cheese for manufacturing are considered as cheddar cheese, washed curd cheese, colby cheese, granular cheese, brick cheese, muenster cheese, and swiss cheese, respectively.

(b) Pasteurized process cheese may be smoked, or the cheese or cheeses from which it is made may be smoked, before comminuting and mixing, or it may contain substances prepared by condensing or precipitating wood smoke.

(c) The emulsifying agent referred to in paragraph (a) of this section is one or any mixture of two or more of the following: Monosodium phosphate, disodium phosphate, dipotassium phosphate, trisodium phosphate, sodium metaphosphate (sodium hexametaphosphate), sodium acid pyrophosphate, tetrasodium pyrophosphate, sodium aluminum phosphate, sodium citrate, potassium citrate, calcium citrate, sodium tartrate, and sodium potassium tartrate, in such quantity that the weight of the solids of such emulsifying agent is not more than 3 percent of the weight of the pasteurized process cheese.

(d) The optional ingredients referred to in paragraph (a) of this section are:

(1) An acidifying agent consisting of one or any mixture of two or more of the following: A vinegar, lactic acid, citric acid, acetic acid, and phosphoric acid, in such quantity that the pH of the pasteurized process cheese is not below 5.3.

(2) Cream, anhydrous milkfat, dehydrated cream, or any combination of two or more of these, in such quantity that the weight of the fat derived therefrom is less than 5 percent of the weight of the pasteurized process cheese.

(3) Water.

(4) Salt.

(5) Harmless artificial coloring.

(6) Spices or flavorings, other than any which singly or in combination with other ingredients simulate the flavor of a cheese of any age or variety.

(7) Pasteurized process cheese in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of not more than 0.2 percent by weight of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, or consisting of not more than 0.3 percent by weight of sodium propionate, calcium propionate, or a combination of sodium propionate and calcium propionate.

(8) Pasteurized process cheese in the form of slices or cuts in consumer-sized packages may contain lecithin as an optional anti-sticking agent in an amount not to exceed 0.03 percent by weight of the finished product.

(9) Safe and suitable enzyme modified cheese.

(e) The name of a pasteurized process cheese for which a definition and standard of identity is prescribed by this section is as follows:

(1) In case it is made from a single variety of cheese, its name is "Pasteurized process _____ cheese", the blank being filled in with the name of the variety of cheese used.

(2) In case it is made from two or more varieties of cheese, its name is "Pasteurized process _____ and _____ cheese", or "Pasteurized process _____ blended with _____ cheese", or "Pasteurized process blend of _____ and _____ cheese", the blanks being filled in with the names of the varieties of cheeses used, in order of predominance by weight; except that:

(i) In case it is made from gruyere cheese and swiss cheese, and the weight of gruyere cheese is not less than 25 percent of the weight of both, it may be designated "Pasteurized process gruyere cheese"; and

(ii) In case it is made of cheddar cheese, washed curd cheese, colby cheese, or granular cheese or any mixture of two or more of these, it may be designated "Pasteurized process American cheese"; or when cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these is combined with other varieties of cheese in the cheese ingredient, any of such cheeses or such mixture may be designated as "American cheese".

The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. Wherever any word or statement emphasizing the name of any ingredient appears on the label (other than in an ingredient statement as specified in paragraph (g) of this section) so conspicuously as to be easily seen under customary conditions of purchase, the full name of the food shall immediately and conspicuously precede or follow such word or statement in type of at least the same size as the type used in such word or statement.

(f) The name of the food shall include a declaration of any flavoring, including smoke and substances prepared by condensing or precipitating wood smoke, that characterizes the product as specified in §101.22 of this chapter and a declaration of any spice that characterizes the product.

(g) The common name of each of the ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter except that:

(1) Artificial coloring need not be declared.

(2) If the cheese ingredient contains cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these, such cheese or such mixture may be designated as "American cheese".

§ 133.170 Pasteurized process cheese with fruits, vegetables, or meats.

(a) Unless a definition and standard of identity specifically applicable is established by another section of this part, a pasteurized process cheese with fruits, vegetables, or meats or mixture of these is a food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for pasteurized process cheese by § 133.169, except that:

(1) Its moisture content may be 1 percent more, and the milk fat content of its solids may be 1 percent less than the limits prescribed by § 133.169 for moisture and fat in the corresponding pasteurized process cheese.

(2) It contains one or any mixture of two or more of the following: Any properly prepared cooked, canned, or dried fruit; any properly prepared cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(3) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by § 133.113(c) is not applicable.

(b) The name of a pasteurized process cheese with fruits, vegetables, or meats is the name prescribed by § 133.169 for the applicable pasteurized process cheese, followed by the term "with_____", the blank being filled in with the common or usual name or names of the fruits, vegetables, or meats used, in order of predominance by weight.

§ 133.171 Pasteurized process pimento cheese.

Pasteurized process pimento cheese is the food which conforms to the definition and standard of identity for pasteurized process cheese with fruits, vegetables, or meats, and is subject to the requirement for label statement of optional ingredients, except that:

(a) Its moisture content is not more than 41 percent, and the fat content of its solids is not less than 49 percent.

(b) The cheese ingredient is cheddar cheese, washed curd cheese, colby cheese, granular cheese or any mixture of two or more of these in any proportion.

(c) For the purposes of this section, cheddar cheese for manufacturing, washed curd cheese for manufacturing, colby cheese for manufacturing, and granular cheese for manufacturing shall be considered as cheddar cheese, washed curd cheese, colby cheese, and granular cheese, respectively.

(d) The only fruit, vegetable, or meat ingredient is pimentos in such quantity that the weight of the solids thereof is not less than 0.2 percent of the weight of the finished pasteurized process pimento cheese.

(e) The optional ingredients designated in § 133.169 (b) and (d) (6) are not used.

(f) The mandatory ingredient pimento need not be declared in the ingredient statement required by § 133.169(g).

§ 133.173 Pasteurized process cheese food.

(a) (1) A pasteurized process cheese food is the food prepared by comminuting and mixing, with the aid of heat, one or more of the optional cheese ingredients prescribed in paragraph (c) of this section, with one or more of the optional dairy ingredients prescribed in paragraph (d) of this section, into a homogeneous plastic mass. One or more of the optional ingredients specified in paragraph (e) of this section may be used.

(2) During its preparation, a pasteurized process cheese food is heated for not less than 30 seconds, at a temperature of not less than 150° F. When tested for phosphatase by the method prescribed in § 133.113(f), the phenol equivalent of 0.25 gram of pasteurized process cheese food is not more than 3 micrograms.

(3) The moisture content of a pasteurized process cheese food is not more than 44 percent, and the fat content is not less than 23 percent.

(4) Moisture and fat are determined by the methods prescribed in § 133.113 (c), except that in determining moisture the loss in weight which occurs in drying for 5 hours, under the conditions prescribed in such method, is taken as the weight of moisture.

(5) The weight of the cheese ingredient prescribed by paragraph (a) (1) of this section constitutes not less than 51 percent of the weight of the finished pasteurized process cheese food.

(6) The weight of each variety of cheese in a pasteurized process cheese food made with two varieties of cheese is not less than 25 percent of the total weight of both, except that the weight of blue cheese, nuworld cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 10 percent of the total weight of both. The weight of each variety of cheese in a pasteurized process cheese food made with three or more varieties of cheese is not less than 15 percent of the total weight of all, except that the weight of blue cheese, nuworld cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 5 percent of the total weight of all. These limits do not apply to the quantity of cheddar cheese, washed curd cheese, colby cheese, and granular cheese in mixtures which are designated as "American cheese" as prescribed in paragraph (h) (5) of this section. Such mixtures are considered as one variety of cheese for the purposes of this subparagraph.

(7) For the purposes of this section, cheddar cheese for manufacturing, washed curd cheese for manufacturing, colby cheese for manufacturing, granular cheese for manufacturing, brick cheese for manufacturing, muenster cheese for manufacturing, and swiss cheese for manufacturing are considered as cheddar cheese, washed curd cheese, colby cheese, granular cheese, brick cheese, muenster cheese, and swiss cheese, respectively.

(b) Pasteurized process cheese food may be smoked, or the cheese or cheeses from which it is made may be smoked, before comminuting and mixing, or it may contain substances prepared by condensing or precipitating wood smoke.

(c) The optional cheese ingredients referred to in paragraph (a) of this section are one or more cheeses of the same or two or more varieties, except cream cheese, neufchatel cheese, cottage cheese, creamed cottage cheese, cook cheese, and skim-milk cheese for manufacturing, and except that hard grating cheese, semisoft part skim cheese, and part-skim spiced cheese are not used alone or in combination with each other as the cheese ingredient.

(d) The optional dairy ingredients referred to in paragraph (a) of this section are cream, milk, skim milk, buttermilk, cheese whey, any of the foregoing from which part of the water has been removed, anhydrous milkfat, dehydrated cream, albumin from cheese whey, and skim milk cheese for manufacturing.

(e) The other optional ingredients referred to in paragraph (a) of this section are:

(1) An emulsifying agent consisting of one or any mixture of two or more of the following: Monosodium phosphate, disodium phosphate, dipotassium phosphate, trisodium phosphate, sodium metaphosphate (sodium hexametaphosphate), sodium acid pyrophosphate, tetrasodium pyrophosphate, sodium aluminum phosphate, sodium citrate, potassium citrate, calcium citrate, sodium tartrate, and sodium potassium tartrate, in such quantity that the weight of the solids of such emulsifying agent is not more than 3 percent of the weight of the pasteurized process cheese food.

(2) An acidifying agent consisting of one or any mixture of two or more of the following: A vinegar, lactic acid, citric acid, acetic acid, and phosphoric acid in such quantity that the pH of the pasteurized process cheese food is not below 5.0.

(3) Water.

(4) Salt.

(5) Harmless artificial coloring.

(6) Spices or flavorings other than any which singly or in combination with other ingredients simulate the flavor of cheese of any age or variety.

(7) Pasteurized process cheese food in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of not more than 0.2 percent by weight of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, or consisting of not more than 0.3 percent by weight of sodium propionate, calcium propionate, or a combination of sodium propionate and calcium propionate.

(8) Pasteurized process cheese food in the form of slices or cuts in consumer-sized packages may contain lecithin as an optional anti-sticking agent in an amount not to exceed 0.03 percent by weight of the finished product.

(9) Safe and suitable enzyme modified cheese.

(f) The name of the food is "Pasteurized process cheese food". The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. Wherever any word or statement emphasizing the name of any ingredient appears on the label (other than in an ingredient statement as specified in paragraph (h) of this section) so conspicuously as to be easily seen under customary conditions of purchase, the full name of the food shall immediately and conspicuously precede or follow such word or statement in type of at least the same size as the type used in such word or statement.

(g) The name of the food shall include a declaration of any flavoring, including smoke and substances prepared by condensing or precipitating wood smoke, that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice that characterizes the product.

(h) The common name of each of the ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that:

(1) Plastic cream and dried cream may be declared as "cream".

(2) Concentrated milk and dried milk may be declared as "milk".

(3) Concentrated skim milk and nonfat dry milk may be declared as "skim milk".

(4) Cheese whey, concentrated cheese whey, and dried cheese whey may be declared as "whey".

(5) If the cheese ingredient contains cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these, such cheese or such mixture may be designated as "American cheese".

§ 133.174 Pasteurized process cheese food with fruits, vegetables, or meats.

(a) Pasteurized process cheese food with fruits, vegetables, or meats, or mixtures of these is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for pasteurized process cheese food by § 133.173, except that:

(1) Its milk fat content is not less than 22 perecnt.

(2) It contains one or any mixture of two or more of the following: Any prop-

erly prepared cooked, canned, or dried fruit; any properly prepared cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(3) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by § 133.113(c) is not applicable.

(b) The name of a pasteurized process cheese food with fruits, vegetables, or meats is "Pasteurized process cheese food with _____", the blank being filled in with the common or usual name or names of the fruits, vegetables, or meats used, in order of predominance by weight.

(c) If the only vegetable ingredient is pimento, and no meat or fruit ingredient is used, the weight of the solids of such pimentos is not less than 0.2 percent of the weight of the finished food. The name of this food is "Pimento pasteurized process cheese food" or "Pasteurized process pimento cheese food".

§ 133.175 Pasteurized cheese spread.

Pasteurized cheese spread is the food which conforms to the definition and standard of identity, and is subject to the requirements of label statement of optional ingredients, prescribed for pasteurized process cheese spread by §133.179, except that no emulsifying agent as prescribed by § 133.179(e) is used.

§ 133.176 Pasteurized cheese spread with fruits, vegetables, or meats.

(a) Pasteurized cheese spread with fruits, vegetables, or meats or mixtures of these is the food which conforms to the definition and standard of identity and is subject to the requirements for label statement of optional ingredients prescribed for pasteurized cheese spread by § 133.175, except that:

(1) It contains one or any mixture of two or more of the following: Any properly prepared cooked, canned, or dried fruit; any properly prepared cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(2) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by § 133.113(c) is not applicable.

(b) The name of a pasteurized cheese spread with fruits, vegetables, or meats is "Pasteurized cheese spread with_____", the blank being filled in with the name or names of the fruits, vegetables, or meats used, in order of predominance by weight.

§ 133.178 Pasteurized neufchatel cheese spread with other foods.

(a)(1) Pasteurized neufchatel cheese spread with other foods is the class of foods each of which is prepared by mixing, with the aid of heat, neufchatel cheese with one or a mixture of two or more properly prepared foods (except other cheeses), such as fresh, cooked, canned, or dried fruits or vegetables; cooked or canned meats; relishes, pickles or other foods suitable for blending with neufchatel cheese. It may contain one or any mixture of two or more of the optional ingredients named in paragraph (b) of this section. The amount of the added food or foods must be sufficient to so differentiate the blend that it does not simulate neufchatel cheese. It is spreadable at 70° F.

(2) During its preparation the mixture is heated for not less than 30 seconds at a temperature of not less than 150° F. When tested for phosphatase by the method prescribed in § 133.113(f), the phenol equivalent of 0.25 gram of such food is not more than 3 micrograms.

(3)(i) No water other than that contained in the ingredients used is added to this food, but the moisture content in no case is more than 65 percent.

(ii) The milk fat is not less than 20 percent by weight of the finished food.

(b) The optional ingredients referred to in paragraph (a) of this section are:

(1)(i) One or any mixture of two or more of the following: Gum karaya, gum tragacanth, carob bean gum, gelatin, algin (sodium alginate), propylene glycol alginate, guar gum, sodium carboxymethylcellulose (cellulose gum), carrageenan, oat gum, or xanthan gum. The total quantity of any such substances, including that contained in the neufchatel cheese, is not more than 0.8 percent by weight of the finished food.

(ii) When one or more of the optional ingredients in paragraph (b)(1)(i) of this section are used, dioctyl sodium sulfosuccinate complying with the requirements of § 172.810 of this chapter may be used in a quantity not in excess of 0.5 percent by weight of such ingredients.

(2) Artificial coloring, unless such addition conceals damage or inferiority or makes the finished food appear better or of greater value than it is.

(3) An acidifying agent consisting of one or a mixture of two or more of the following: A vinegar, acetic acid, lactic acid, citric acid, phosphoric acid.

(4) A sweetening agent consisting of one or a mixture of two or more of the following: Sugar, dextrose, corn sirup, corn sirup solids, glucose sirup, glucose sirup solids, maltose, malt sirup, hydrolyzed lactose.

(5) Cream, milk, skim milk, buttermilk, cheese whey, any of the foregoing from which part of the water has been removed, anhydrous milkfat, dehydrated cream, and albumin from cheese whey.

(c) The name of the food is "pasteurized Neufchâtel cheese spread with _____" or "pasteurized Neufchâtel cheese spread and _____", the blank being filled in with the common names of the foods added, in order of predominance by weight. The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. Wherever any word or statement emphasizing the name of any ingredient appears on the label (other than in an ingredient statement as specified in paragraph (d) of this section) so conspicuously as to be easily seen under customary conditions of purchase, the full name of the food shall immediately and conspicuously precede or follow such word or statement in type of at least the same size as the type used in such word or statement.

(d) The common name of each of the ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that:

(1) Plastic cream and dried cream may be declared as "cream".

(2) Concentrated milk and dried milk may be declared as "milk".

(3) Concentrated skim milk and nonfat dry milk may be declared as "skim milk".

§ 133.179 Pasteurized process cheese spread.

(a)(1) Pasteurized process cheese spread is the food prepared by comminuting and mixing, with the aid of heat, one or more of the optional cheese ingredients prescribed in paragraph (c) of this section, with or without one or more of the optional dairy ingredients prescribed in paragraph (d) of this section, with one or more of the emulsifying agents prescribed in paragraph (e) of this section, and with or without one or more of the optional ingredients prescribed by paragraph (f) of this section, into a homogeneous plastic mass, which is spreadable at 70° F.

(2) During its preparation, a pasteurized process cheese spread is heated for not less than 30 seconds at a temperature of not less than 150° F. When tested for phosphatase by the method prescribed in § 133.113(f) the phenol equivalent of 0.25 gram of pasteurized process cheese spread is not more than 3 micrograms.

(3) The moisture content of a pasteurized process cheese spread is more than 44 percent but not more than 60 percent, and the milk fat content is not less than 20 percent.

(4) Moisture and fat are determined by the methods prescribed in § 133.113 (c), except that in determining moisture the loss in weight which occurs in drying for 5 hours under the conditions prescribed in such method, is taken as the weight of the moisture.

(5) The weight of the cheese ingredient referred to in paragraph (a)(1) of this section constitutes not less than 51 percent of the weight of the pasteurized process cheese spread.

(6) The weight of each variety of cheese in a pasteurized process cheese spread made with two varieties of cheese is not less than 25 percent of the total weight of both, except that the weight of blue cheese, nuworld cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 10 percent of the total weight of both. The weight of each variety of cheese in a pasteurized process cheese spread made with three or more varieties of cheese is not less than 15 percent of the total weight of all, except that the weight of blue cheese, nuworld cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 5 percent of the total weight of all. These limits do not apply to the quantity of cheddar cheese, washed curd cheese, colby cheese, and granular cheese in mixtures which are designated as "American

cheese" as prescribed in paragraph (i) (5) of this section. Such mixtures are considered as one variety of cheese for the purposes of this paragraph (a) (6).

(7) For the purposes of this section, cheddar cheese for manufacturing, washed curd cheese for manufacturing, colby cheese for manufacturing, granular cheese for manufacturing, brick cheese for manufacturing, muenster cheese for manufacturing, and swiss cheese for manufacturing are considered as cheddar cheese, washed curd cheese, colby cheese, granular cheese, brick cheese, muenster cheese, and swiss cheese, respectively.

(b) Pasteurized process cheese spread may be smoked, or the cheese or cheeses from which it is made may be smoked, before comminuting and mixing, or it may contain substances prepared by condensing or precipitating wood smoke.

(c) The optional cheese ingredients referred to in paragraph (a) of this section are one or more cheeses of the same or two or more varieties, except that skim-milk cheese for manufacturing may not be used, and except that cream cheese, neufchatel cheese, cottage cheese, creamed cottage cheese, cook cheese, hard grating cheese, semisoft part-skim cheese, and part-skim spiced cheese are not used, alone or in combination with each other, as the cheese ingredient.

(d) The optional dairy ingredients referred to in paragraph (a) of this section are cream, milk, skim milk, buttermilk, cheese whey, any of the foregoing from which part of the water has been removed, anhydrous milkfat, dehydrated cream, albumin from cheese whey, and skim milk cheese for manufacturing.

(e) The emulsifying agents prescribed in paragraph (a) of this section are one or any mixture of two or more of the following: Monosodium phosphate, disodium phosphate, dipotassium phosphate, trisodium phosphate, sodium metaphosphate (sodium hexametaphosphate), sodium acid pyrophosphate, tetrasodium pyrophosphate, sodium aluminum phosphate, sodium citrate, potassium citrate, calcium citrate, sodium tartrate, and sodium potassium tartrate, in such quantity that the weight of the solids of such emulsifying agent is not more than 3 percent of the weight of the pasteurized process cheese spread.

(f) The other optional ingredients referred to in paragraph (a) of this section are:

(1) (i) One or any mixture of two or more of the following: Carob bean gum, gum karaya, gum tragacanth, guar gum, gelatin, sodium carboxymethylcellulose (cellulose gum), carrageenan, oat gum, algin (sodium alginate), propylene glycol alginate, or xanthan gum. The total weight of such substances is not more than 0.6 percent of the weight of the finished food.

(ii) When one or more of the optional ingredients in paragraph (f) (1) (i) of this section are used, dioctyl sodium sulfosuccinate complying with the requirements of § 172.810 of this chapter may be used in a quantity not in excess of 0.5 percent by weight of such ingredients.

(2) An acidifying agent consisting of one or any mixture of two or more of the following: A vinegar, lactic acid, citric acid, acetic acid, and phosphoric acid, in such quantity that the pH of the pasteurized process cheese spread is not below 4.0.

(3) A sweetening agent consisting of one or any mixture of two or more of the following: Sugar, dextrose, corn sugar, corn sirup, corn sirup solids, glucose sirup, glucose sirup solids, maltose, malt sirup, and hydrolyzed lactose, in a quantity necessary for seasoning.

(4) Water.

(5) Salt.

(6) Harmless artificial coloring.

(7) Spices or flavorings other than any which singly or in combination with other ingredients simulate the flavor of a cheese of any age or variety.

(8) Pasteurized process cheese spread in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.2 percent by weight, calculated as sorbic acid or consisting of not more than 0.3 percent by weight of sodium propionate, calcium propionate, or a combination of sodium propionate and calcium propionate.

(9) Pasteurized process cheese spread in consumer-sized packages may contain lecithin as an optional anti-sticking agent in an amount not to exceed 0.03 percent by weight of the finished product.

(10) Safe and suitable enzyme modified cheese.

(g) The name of the food is "pasteurized process cheese spread." The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. Wherever any word or statement emphasizing the name of any ingredient appears on the label (other than in an ingredient statement as specified in paragraph (i) of this section) so conspicuously as to be easily seen under customary conditions of purchase, the full name of the food shall immediately and conspicuously precede or follow such word or statement in type of at least the same size as the type used in such word or statement.

(h) The name of the food shall include a declaration of any flavoring, including smoke and substances prepared by condensing or precipitating wood smoke, that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice that characterizes the product.

(i) The common name of each of the ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that:

(1) Plastic cream and dried cream may be declared as "cream".

(2) Concentrated milk and dried milk may be declared as "milk".

(3) Concentrated skim milk and nonfat dry milk may be declared as "skim milk".

(4) Cheese whey, concentrated cheese whey, and dried cheese whey may be declared as "whey".

(5) If the cheese ingredient contains cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these, such cheese or such mixture may be designated as "American cheese".

§ 133.180 Pasteurized process cheese spread with fruits, vegetables, or meats.

(a) Pasteurized process cheese spread with fruits, vegetables, or meats or mixtures of these is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for pasteurized process cheese spread by § 133.179, except that:

(1) It contains one or any mixture of two or more of the following: Any properly prepared cooked, canned, or dried fruit; any properly prepared cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(2) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by § 133.113(c) is not applicable.

(b) The name of a pasteurized process cheese spread with fruits, vegetables, or meats is "Pasteurized process cheese spread with _____", the blank being filled in with the name or names of the fruits, vegetables, or meats used, in order of predominance by weight.

§ 133.181 Provolone and pasta filata cheese.

(a) Provolone cheese, pasta filata cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It has a stringy texture, and may be made in several shapes. It contains not more than 45 percent of moisture, and its solids contain not less than 45 percent of milk fat, as determined by the methods prescribed in § 133.113(c). If the milk used is not pasteurized, the cheese so made is held at a temperature of not less than 35° F for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial blue or green coloring in a quantity which neutralizes any natural yellow coloring in the curd may be added. Sufficient rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is cut, stirred, and heated so as to promote

and regulate the separation of whey from the curd. The whey is drained off and the curd is matted and cut, immersed in hot water, and kneaded and stretched until it is smooth and free from lumps. Then it is cut and molded. During the molding the curd is kept sufficiently warm to cause proper sealing of the surface. The molded curd is then firmed by immersion in cold water, salted in brine, and dried. Some shapes may be encased in ropes or twine before drying. Provolone cheese may be smoked or it may have added to it a clear aqueous solution prepared by condensing or precipitating wood smoke in water. It is given some additional curing and covered with paraffin or similar wax. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of provolone cheese may be added during the procedure in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Provolone cheese shall be deemed not to have been made from pasteurized milk if 0.25 gram shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 133.113(f).

(3) Such milk may be bleached by the use of benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate; but the weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, sufficient vitamin A is added to the curd to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(d) Provolone cheese in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e)(1) The name "provolone cheese" ("pasta filata cheese") may include the common name of the shape of the cheese, such as "salami provolone". If provolone cheese is not smoked, the name includes the words "not smoked". If a clear aqueous solution prepared by condensing or precipitating wood smoke in water is added to the provolone cheese, the name is immediately followed by the words "with added smoke flavoring" with all words in this phrase of the same type size, style, and color without intervening written, printed, or graphic matter.

(2)(i) If provolone cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(ii) If the milk used is bleached, the label shall bear the statement "Milk bleached with benzoyl peroxide".

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed by this section, showing the optional ingredient used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter, except for the statement "with added smoke flavoring" as set forth in paragraph (e)(1) of this section.

§ 133.182 Soft ripened cheeses.

(a) The cheeses for which definitions and standards of identity are prescribed by this section are soft ripened cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. Their solids contain not less than 50 percent of milk fat, as determined by the method prescribed therefor in § 133.113(c). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-producing bacteria, present in such milk or added thereto. Sufficient rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. After coagulation the mass is so treated as to promote and regulate the separation of whey and curd. Such treatment may include one or more of the following: Cutting, stirring, heating, dilution with water or brine. The whey, or part of it, is drained off, and the curd is collected and shaped. It may be placed in forms, and may be pressed. Harmless flavor-producing microorganisms may be added. It is cured under conditions suitable for development of biological curing agents on the surface of the cheese, and the curing is conducted so that the cheese cures from the surface toward the center. Salt may be added during the procedure. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of soft ripened cheeses may be added, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water, in a quantity sufficient to reconstitute any such concentrated or dried products used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction.

(d) The name of each soft ripened cheese for which a definition and standard of identity is prescribed by this section is "Soft ripened cheese", preceded or followed by:

(1) The specific common or usual name of such soft ripened cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name which is not false or misleading in any particular.

(e) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement "made from _____", the blank being filled in with the name or names of the milk used, in order of predominance by weight.

§ 133.183 Romano cheese.

(a) Romano cheese is the food prepared from cow's milk or sheep's milk or goat's milk or mixtures of two or all of these and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It grates readily, and has a granular texture and a hard and brittle rind. It contains not more than 34 percent of moisture, and its solids contain not less than 38 percent of milk fat, as determined by the methods prescribed in § 133.113(c). It is cured for not less than 5 months.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of

harmless lactic-acid-producing bacteria present in such milk or added thereto. Harmless artificial blue or green coloring in a quantity which neutralizes any natural yellow coloring in the curd may be added. Rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to be a semisolid mass. The mass is cut into particles no larger than corn kernels, stirred, and heated to a temperature of about 120° F. The curd is allowed to settle to the bottom of the kettle or vat, and is then removed and drained for a short time, packed in forms or hoops, and pressed. The pressed curd is salted by immersing in brine for about 24 hours and is then removed from the brine and the surface allowed to dry. It is then alternately rubbed with salt and washed at intervals. It may be perforated with needles. It is finally dry-cured. During curing it is turned and scraped. The surface may be rubbed with vegetable oil. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of romano cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) (1) For the purposes of this section, the word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any such concentrated or dried products used.

(2) Such milk may be bleached by the use of benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate; but the weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk bleached, and the weight of the potassium alum, calcium, sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, sufficient vitamin A is added to the curd to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(d) Romano cheese in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e) When romano cheese is made solely from cow's milk, the name of such cheese is "Romano cheese made from cow's milk", and may be preceded by the word "Vaccino" (or "Vacchino"); when made solely from sheep's milk, the name is "Romano cheese made from sheep's milk", and may be preceded by the word "Pecorina"; when made solely from goat's milk, the name is "Romano cheese made from goat's milk", and may be preceded by the word "Caprino"; and when a mixture of two or all of the milks specified in this section is used, the name of the cheese is "Romano cheese made from _____", the blank being filled in with the names of the milks used, in order of predominance by weight.

(f) (1) If the milk used is bleached, the label shall bear the statement "Milk bleached with benzoyl peroxide".

(2) If romano cheese in sliced or cut form contains an optional mold-inhibiting ingredient as provided for in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed by this section, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed or graphic matter.

§ 133.184 Roquefort, sheep's milk blue-mold, and blue-mold cheese from sheep's milk.

(a) Roquefort cheese, sheep's milk blue-mold cheese, blue mold cheese from sheep's milk, is the food prepared from sheep's milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It is characterized by the presence of bluish-green mold throughout the cheese. It contains not more than 45 percent moisture, and its solids contain not less than 50 percent milk fat, as determined by the methods prescribed in § 133.113 (c). It is not less than 60 days old.

(b) Milk, which may be pasteurized, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, is added to set the milk to a semisolid mass. The mass is cut into smaller portions and allowed to stand for a time. The mixed curd and whey is placed in forms permitting further drainage of whey. Spores of the mold *Penicillium roqueforti* are added. The forms are turned several times during drainage. When sufficiently drained, the shaped curd is removed from the forms and salted with dry salt or brine. Perforations are then made in the shaped curd, and it is held at a temperature of approximately 50° F, with relative humidity of 90 to 95 percent, until the characteristic mold growth has developed. During storage the surface of the cheese is scraped, if necessary, to remove surface growth of undesirable microorganisms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of roquefort cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section, the word "milk" means sheep's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto sheep's milk cream or skimmed sheep's milk.

§ 133.185 Samsoe cheese.

(a) Samsoe cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. The shape of the cheese is flat cylindrical. Its weight is approximately 30 pounds (14 kilograms); its diameter is approximately 17 inches (44 centimeters); and its height is approximately 4 inches (10 centimeters). It has a small amount of eye formation of approximately uniform size of about $\frac{1}{16}$-inch (8 millimeters). It contains not more than 41 percent of moisture, and its solids contain not less than 45 percent of milk fat, as determined by the methods prescribed in § 133.113(c). The cheese so made is cured at a temperature of not less than 35° F for not less than 60 days. The surface may be covered with plain or colored paraffin or other tightly adhering coating.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the milk, is added to set the milk to a semisolid mass. After coagulation the mass is cut into small cube-shaped pieces with sides approximately $\frac{3}{8}$-inch (1 centimeter). The mass is stirred and heated to about 102° F, and so handled by further stirring, heating, dilution with water, and salting as to promote and regulate the separation of curd and whey. When the desired curd is obtained, it is transferred to forms permitting drainage of whey. During drainage, the curd is pressed. After drainage, the curd is removed from the forms and is further salted by immersing in a concentrated salt solution for about 3 days. The curd

is then cured at a temperature of from 60° to 70° F for 3 to 5 weeks to obtain the desired eye formation. Further curing is conducted at a lower temperature.

(c) For the purposes of this section the word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto cream or skim milk.

§ 133.186 Sap sago cheese.

(a) Sap sago cheese is the food prepared from the skim milk of cows and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. It has a pale-green color, and is made in the shape of a truncated cone. It contains not more than 38 percent of moisture, as determined by the method prescribed in § 133.113(c).

(b) Skim milk is allowed to become sour, and is heated to boiling temperature, with stirring. Cold buttermilk may be added. Sufficient sour whey is added to precipitate the casein. The curd is removed, spread out in boxes, and pressed, and while under pressure is allowed to drain and ferment. It is ripened for not less than 5 weeks. The ripened curd is dried and ground, salt and dried clover of the species *Melilotus coerulea* are added. The mixture is shaped into truncated cones. It is then cured for not less than 5 months.

§ 133.187 Semisoft cheeses.

(a) The cheeses for which definitions and standards of identity are prescribed by this section are semisoft cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. They contain more than 39 percent, but not more than 50 percent, of moisture, and their solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 133.113(c). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-producing bacteria, present in such milk or added thereto. Sufficient rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. After coagulation the mass is so treated as to promote and regulate the separation of whey and curd. Such treatment may include one or more of the following: cutting, stirring, heating, dilution with water or brine. The whey, or part of it, is drained off, and the curd is collected and shaped. It may be placed in forms, and may be pressed. Harmless flavor-producing microorganisms may be added. It may be cured in a manner to promote the growth of biological curing agents. Salt may be added during the procedure. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of semisoft cheese may be added, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom, or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any concentrated or dried products used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. A semisoft cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm shows a phenol equivalent of more than 5 micrograms when tested by the method prescribed in § 133.113(f).

(d) Semisoft cheeses in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e) The name of each semisoft cheese for which a definition and standard of identity is prescribed by this section is "Semisoft cheese", preceded or followed by:

(1) The specific common or usual name of such semisoft cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name which is not false or misleading in any particular.

(f)(1) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement "made from _____", the blank being filled in with the name or names of the milk used, in order of predominance by weight.

(2) If semisoft cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed by this section, showing the optional ingredient used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 133.188 Semisoft part-skim cheeses.

(a) The cheeses for which definitions and standards of identity are prescribed by this section are semisoft part-skim cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from partly skimmed milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. They contain not more than 50 percent of moisture, and their solids contain not less than 45 percent, but less than 50 percent, of milk fat, as determined by the methods set forth in § 133.113(c). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F, for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-producing bacteria, present in such milk or added thereto. Sufficient rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. After coagulation the mass is so treated as to promote and regulate the separation of whey and curd. Such treatment may include one or more of the following: Cutting, stirring, heating, dilution with water or brine. The whey, or part of it, is drained off, and the curd is collected and shaped. It may be placed in forms, and it may be pressed. Harmless flavor-producing microorganisms may be added. It may be cured in a manner to promote the growth of biological curing agents. Salt may be added during the procedure. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of semisoft part-skim cheese may be added in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products

from sheep's milk; water in a quantity sufficient to reconstitute any such concentrated or dried products used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. A semisoft part-skim cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 5 micrograms when tested by the method prescribed in § 133.113(f).

(d) Semisoft part-skim cheeses in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e) The name of each semisoft part-skim cheese for which a definition and standard of identity is prescribed by this section is "Semisoft part-skim cheese," preceded or followed by:

(1) The specific common or usual name of such semisoft cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name which is not false or misleading in any particular.

(f)(1) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement "made from _____", the blank being filled in with the name or names of the milk used, in order of predominance by weight.

(2) If semi-soft part-skim cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative ", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed by this section, showing the optional ingredient used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 133.189 Skim milk cheese for manufacturing.

(a) Skim milk cheese for manufacturing is the food prepared from skim milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 50 percent of moisture, as determined by the method therefor prescribed in § 133.113(c). It is coated with blue-colored paraffin or other tightly adhering coating, colored blue.

(b) Skim milk or the optional dairy ingredients specified in paragraph (c) of this section, which may be pasteurized, and which may be warmed, are subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the skim milk, is added to set the skim milk to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. The whey is drained off, and the curd is matted into a cohesive mass. Proteins from the whey may be incorporated. The mass is cut into slabs which are so piled and handled as to promote the drainage of whey and the development of acidity. The slabs are then cut into pieces, which may be rinsed by pouring or sprinkling water over them, with free and continuous drainage; but the duration of such rinsing is so limited that only the whey on the surface of such pieces is removed. The curd is salted, stirred, further drained, and pressed into forms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of skim milk cheese for manufacturing may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) The optional dairy ingredients referred to in paragraph (b) of this section are: Skim milk or concentrated skim milk or nonfat dry milk or a mixture of any two or more of these, with water in a quantity not in excess of that sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(d) For the purposes of this section, "skim milk" means cow's milk from which the milk fat has been separated.

§ 133.190 Spiced cheeses.

(a) The cheeses for which definitions and standards of identity are prescribed by this section are spiced cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from milk and the other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. Their solids contain not less than 50 percent of milk fat as determined by the method therefor prescribed in § 133.113(c). They contain one or a mixture of two or more spices, except any which singly or in combination with other ingredients simulate the flavor of a cheese of any age or variety, in an amount not less than 0.015 ounce per pound of cheese, and may contain spice oils. If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is divided into smaller portions, and so handled by stirring, heating, and diluting with water or salt brine as to promote and regulate the separation of whey and curd. The whey is drained off. The curd is removed, and may be further drained. The curd is then shaped into forms, and may be pressed. At some time during the procedure, spices are added so as to be evenly distributed through the finished cheese. Spice oils may be added. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of spiced cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used. Harmless flavor-producing microorganisms may be added, and curing may be conducted under suitable conditions for the development of biological curing agents.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any such concentrated or dried products used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Spiced cheeses shall be deemed not to have been made from pasteurized milk if 0.25 gram shows a phenol equivalent of more than 3 micrograms, when tested by the method prescribed in § 133.113(f).

(d) Spiced cheeses in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e) The name of each spiced cheese for which a definition and standard of identity is prescribed by this section is

"Spiced cheese", preceded or followed by:

(1) The specific common or usual name of such spiced cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name that is not false or misleading in any particular.

(f)(1) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement "made from _____", the blank being filled in with the name or names of the milk used, in order of predominance by weight.

(2) If spiced cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed by this section, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 133.191 Part-skim spiced cheeses.

Part-skim spiced cheeses conform to the definition and standard of identity, and are subject to the requirements for label statement of optional ingredients, prescribed for spiced cheeses by § 133.190, except that their solids contain less than 50 percent, but not less than 20 percent, of milk fat.

§ 133.193 Spiced, flavored standardized cheeses.

(a) Except as otherwise provided for herein and in applicable sections in this part, a spiced or flavored standardized cheese conforms to the applicable definitions, standard of identity and requirements for label statement of optional ingredients prescribed for that specific natural cheese variety promulgated pursuant to section 401 of the act. In addition a spiced and/or flavored standardized cheese shall contain one or more safe and suitable spices and/or flavorings, in such proportions as are reasonably required to accomplish their intended effect: *Provided*, That no combination of ingredients shall be used to simulate the flavor of cheese of any age or variety.

(b) The name of a spiced or flavored standardized cheese shall include in addition to the varietal name of the natural cheese, a declaration of any flavor and/or spice that characterizes the food, in the manner prescribed in § 101.22 of this chapter.

§ 133.195 Swiss and emmentaler cheese.

(a) Swiss cheese, emmentaler cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It has holes, or eyes, developed throughout the cheese. It contains not more than 41 percent of moisture, and its solids contain not less than 43 percent of milk fat, as determined by the methods prescribed in § 133.113(c). It is not less than 60 days old.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto; harmless propionic-acid-producing bacteria may also be added. Authorized artificial coloring may be added. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the milk, is added to set the milk to a semisolid mass. The mass is cut into particles similar in size to wheat kernels. For about 30 minutes the particles are alternately stirred and allowed to settle. The temperature is raised to about 126° F. Stirring is continued until the curd becomes firm. The acidity of the whey at this point, calculated as lactic acid, does not exceed 0.13 percent. The curd is transferred to hoops or forms and pressed until the desired shape and firmness are obtained. The cheese is then salted by immersing it in a saturated salt solution for about 3 days. It is then held at a temperature of about 50° F to 60° F for a period of 5 to 10 days, after which it is held at a temperature of about 75° F until it is approximately 30 days old, or until the so-called eyes form. Salt, or a solution of salt in water, is added to the surface of the cheese at some time during the curing process. The cheese is then stored at a lower temperature for further curing. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of swiss cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c)(1) For the purposes of this section, the word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto cream or skim milk. Such milk may be bleached by the use of benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate; but the weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk bleached, and the weight of potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If the milk is bleached in this manner, sufficient vitamin A is added to the curd to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(2) During the cheese-making process the milk may be treated as provided in § 133.113(e)(3).

(d) Swiss cheese in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e)(1)(i) If swiss cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement "_____ added to retard mold growth" or "_____ added as a preservative", the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(ii) If the milk used is bleached, the label shall bear the statement "Milk bleached with benzoyl peroxide".

(2) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in this section, showing the optional ingredient used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 133.196 Swiss cheese for manufacturing.

Swiss cheese for manufacturing conforms to the definition and standard of identity prescribed for swiss cheese by § 133.195, except that the holes, or eyes, have not developed throughout the entire cheese, and the provisions of paragraph (d) of that section do not apply; however, the labeling requirements of paragraph (e)(2) of that section do apply.

PART 135—FROZEN DESSERTS

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Frozen Desserts

Sec.

135.10 Frozen custard.
135.20 Fruit sherbets.
135.30 Ice cream.
135.40 Ice milk.
135.50 Mellorine.
135.65 Nonfruit sherbets.
135.70 Nonfruit water ices.
135.90 Water ices.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046 as amended, 1055–1056 as amended (21 U.S.C. 341, 371).

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Frozen Desserts

§ 135.10 Frozen custard.

Frozen custard, french ice cream, french custard ice cream conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for ice cream by § 135.30, except that one or more of the optional egg

ingredients permitted by § 135.30(f)(1) are used in such quantity that the total weight of egg yolk solids therein is not less than 1.4 percent of the weight of the finished frozen custard: *Provided, however,* That when the ingredients named in § 135.30(b) (3) through (8), inclusive, are used, the content of egg yolk solids may be reduced in proportion to the bulky ingredient or ingredients added, under the conditions prescribed by § 135.30(a) for reduction in milk fat and total milk solids; but in no case is the content of egg yolk solids less than 1.12 percent.

§ 135.20 Fruit sherbets.

(a) Fruit sherbets are the foods each of which is prepared by freezing, while stirring, a mix composed of one or more of the optional characterizing fruit ingredients specified in paragraph (b) of this section and one or more of the optional ingredients specified in paragraph (c) of this section, sweetened with one or more of the optional sweetening ingredients specified in paragraph (d) of this section. One or more of the optional ingredients specified in paragraph (e) of this section may be used, subject to the conditions hereinafter set forth. The mix of combined dairy ingredients, with or without other ingredients, is pasteurized. The titratable acidity of the finished fruit sherbet, calculated as lactic acid, is not less than 0.35 percent. The mix with or without added water may be seasoned with salt, and may be homogenized. The optional dairy ingredients used and the content of milk fat and nonfat milk solids therein are such that the weight of milk fat is not less than 1 percent and not more than 2 percent, and the weight of total milk solids is not less than 2 percent and not more than 5 percent of the weight of the finished fruit sherbet. The optional caseinates specified in paragraph (e)(7) of this section are not deemed to be milk solids. The finished fruit sherbet weighs not less than 6 pounds to the gallon: except that when the optional ingredient microcrystalline cellulose specified in paragraph (e)(11) of this section is used, the finished fruit sherbet weighs not less than 6 pounds to the gallon, exclusive of the weight of the microcrystalline cellulose.

(b) The optional fruit characterizing ingredients referred to in paragraph (a) of this section are any mature fruit or the juice of any mature fruit. The fruit or fruit juice used may be fresh, frozen, canned, concentrated, or partially or wholly dried. The fruit may be thickened with pectin or other of the optional ingredients named in paragraph (e)(2) of this section, subject to the restriction on the total quantity of such substances in fruit sherbets prescribed in that paragraph. The fruit is prepared by the removal of pits, seeds, skins, and cores, where such removal is usual in preparing that kind of fruit for consumption as fresh fruit. The fruit may be screened, crushed, or otherwise comminuted. It may be acidulated with citric acid, ascorbic acid, or phosphoric acid. In the case of concentrated fruit or fruit juices, from which part of the water is removed, substances contributing flavor volatilized during water removal may be condensed and reincorporated in the concentrated fruit or fruit juice. In the case of citrus fruits, the whole fruit, including the peel but excluding the seeds, may be used, and in the case of citrus juice or concentrated citrus juices, cold-pressed citrus oil may be added thereto in an amount not exceeding that which would have been obtained if the whole fruit had been used. The quantity of fruit ingredients used is such that, in relation to the weight of the finished sherbet, the weight of fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content), is not less than 2 percent in the case of citrus sherbets, 6 percent in the case of berry sherbets, and 10 percent in the case of sherbets prepared with other fruits. For the purposes of this section, tomatoes and rhubarb are considered as kinds of fruit.

(c) The optional dairy ingredients referred to in paragraph (a) of this section are: Cream, dried cream, plastic cream (sometimes known as concentrated milk fat), butter, butter oil, milk, concentrated milk, evaporated milk, superheated condensed milk, sweetened condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, condensed skim milk, superheated condensed skim milk, sweetened condensed skim milk, sweetened condensed part-skim milk, nonfat dry milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, skim milk that has been concentrated and from which part of the lactose has been removed by crystallization, concentrated cheese whey, and dried cheese whey. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent, calculated as lactic acid. The term "milk" as used in this section means cow's milk. Dried cheese whey is uniformly light in color, free from brown and black scorched particles, and has an alkalinity of ash, not more than 225 milliliters 0.1N HCl per 100 grams, a bacterial count of not more than 50,000 per gram, and, as adjusted with water to a total solids content of 6.5 percent, a titratable acidity of not more than 0.16 percent calculated as lactic acid. Concentrated cheese whey has an alkalinity of ash, not more than 115 milliliters 0.1N HCl per 100 grams, a bacterial count of not more than 50,000 per gram, and, as adjusted with water to a total solids content of 6.5 percent, a titratable acidity of not more than 0.18 percent, calculated as lactic acid.

(d) The optional sweetening ingredients referred to in paragraph (a) of this section are: Sugar (sucrose), dextrose, invert sugar (paste or sirup), glucose sirup, dried glucose sirup, corn sirup, dried corn sirup, malt sirup, malt extract, dried malt sirup, dried malt extract, maltose sirup, dried maltose sirup.

(e) Other optional ingredients referred to in paragraph (a) of this section are:

(1) Liquid eggs, frozen eggs, dried eggs, egg yolks, frozen yolks, dried yolks; but the weight of egg yolk solids therein is less than 0.5 percent of the weight of the finished fruit sherbet.

(2) Agar-agar, algin (sodium alginate), calcium sulfate, egg white, gelatin, gum acacia, guar seed gum, gum karaya, locust bean gum, oat gum, gum tragacanth, hydroxypropyl methylcellulose, carrageenan, salts of carrageenan, furcelleran, salts of furcelleran, lecithin, pectin, psyllium seed husk, sodium carboxymethylcellulose. The total weight of the solids of any such ingredient used singly or of any combination of two or more such ingredients used (including any such ingredient added separately to the fruit ingredient) is not more than 0.5 percent of the weight of the finished fruit sherbet. Such ingredients may be added in admixture with dextrin, propylene glycol, or glycerin.

(3) Monoglycerides or diglycerides or both of fat-forming fatty acids. The total weight of such ingredients is not more than 0.2 percent of the weight of the finished fruit sherbet. If the preparation used is one having a high proportion of monoglycerides (over 90 percent), it may be preblended with edible fat, but the amount of such fat does not exceed 20 percent by weight of the blend, and the total amount of the blend used does not exceed 0.2 percent of the weight of the finished fruit sherbet.

(4) Polysorbate 65, polysorbate 80, or both (complying with the provisions of § 172.838 and § 172.840 of this chapter including the limit on either used separately or both used in combination of not more than 0.1 percent by weight of the finished frozen dessert).

(5) Propylene glycol alginate (complying with the provisions of § 172.858 of this chapter including the limit of not more than 0.5 percent by weight of the finished frozen dessert).

(6) Citric acid, tartaric acid, malic acid, lactic acid, ascorbic acid, phosphoric acid, or any combination of two or more of these in such quantity as seasons the finished food.

(7) Casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate, sodium caseinate.

(8) Any natural food flavoring.

(9) Any artificial flavoring.

(10) Coloring, including artificial coloring.

(11) Microcrystalline cellulose, in a quantity not to exceed 0.5 percent of the weight of the finished fruit sherbet.

(12) When one or more of the optional thickening ingredients in paragraph (e)(2) or (5) of this section are used, dioctyl sodium sulfosuccinate complying with the requirements of §172.810 of this chapter may be used in a quantity not in excess of 0.5 percent by weight of such ingredients.

(f) The name of each such fruit sherbet is "_____ sherbet", the blank being filled in with the common name of the fruit or fruits from which the fruit ingredients used are obtained. When the names of two or more fruits are included, such names shall be arranged in order of predominance, if any, by weight of the respective fruit ingredients used.

(g) When the optional ingredients artificial coloring or artificial flavoring are used in fruit sherbet they shall be named on the labels as follows:

(1) The label shall designate artificial coloring by the statement "artificially colored", "artificial coloring added", "with added artificial coloring", or "_____ an artificial color added", the blank being filled in with the name of the artificial coloring used.

(2) The label shall designate artificial flavoring by the statement "artificially flavored", "artificial flavoring added", "with added artificial flavoring", or "_____ an artificial flavor added", the blank being filled in with the name of the artificial flavoring used.

(3) Whenever artificial flavoring is not added as such but as a component of some other ingredient, the label shall include the statement "_____ artificially flavored", the blank being filled in with the name of such other ingredient.

(4) When the optional ingredient microcrystalline cellulose specified in paragraph (e) (11) of this section is used, the label shall bear the statement "microcrystalline cellulose added" or "with added microcrystalline cellulose".

Label statements may be combined, as for example, "with added artificial flavoring and artificial coloring".

(h) Where one or more of the optional ingredients artificial coloring or artificial flavoring are used and there appears on the label any representation as to the fruit or fruits in the sherbet, such representation shall be immediately and conspicuously accompanied by appropriate label statements as prescribed in paragraph (g) of this section, showing the optional ingredients used.

(i) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements specified in this section, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter.

§ 135.30 Ice cream.

(a) Ice cream is the food prepared by freezing, while stirring, a pasteurized mix composed of one or more of the optional ingredients specified in paragraph (c) of this section, sweetened with one or more of the optional sweetening ingredients specified in paragraph (d) of this section. One or more of the optional characterizing ingredients specified in paragraph (b) of this section and one or more of the optional ingredients specified in paragraph (d) (5) to (10) may be used to characterize the ice cream. One or more of the optional caseinates specified in paragraph (e) and one or more of the optional ingredients specified in paragraph (f) of this section may be used, subject to the conditions hereinafter set forth. The mix may be seasoned with salt, and may be homogenized. The kind and quantity of optional dairy ingredients used, as specified in paragraph (c) of this section, and the content of milk fat and nonfat milk solids therein, are such that the weights of milk fat and total milk solids are not less than 10 percent and 20 percent, respectively, of the weight of the finished ice cream; but in no case shall the content of milk solids not fat be less than 6 percent, except that when one or more of the bulky optional ingredients as specified in paragraph (b) (3) to (8), inclusive, of this section, are used, the weights of milk fat and total milk solids (exclusive of such fat and solids in any malted milk used) are not less than 10 percent and 20 percent, respectively, of the remainder obtained by subtracting the weight of such optional ingredients, modified as prescribed in this paragraph, from the weight of the finished ice cream; but in no case is the weight of milk fat or total milk solids less than 8 percent and 16 percent, respectively, of the weight of the finished ice cream. The optional caseinates specified in paragraph (e) of this section are not deemed to be milk solids. In calculating the reduction of milk fat and total milk solids from the use of bulky optional ingredients, chocolate and cocoa solids used shall be considered the bulky ingredients of paragraph (b) (3) of this section. In order to make allowance for additional sweetening ingredients needed when bulky ingredients are used, the weight of chocolate or cocoa solids may be multiplied by 2.5; the weight of fruit or nuts used may be multiplied by 1.4; and the weight of partially or wholly dried fruits or fruit juices may be multiplied by appropriate factors to obtain the original weights before drying and this weight multiplied by 1.4. The finished ice cream contains not less than 1.6 pounds of total solids to the gallon and weighs not less than 4.5 pounds to the gallon; except that when the optional ingredient microcrystalline cellulose specified in paragraph (f) (6) of this section is used, the finished ice cream contains not less than 1.6 pounds of total solids to the gallon and weighs not less than 4.5 pounds to the gallon exclusive, in both cases, of the weight of the microcrystalline cellulose. Artificial flavoring in any chocolate, cocoa, confectionery, or other ingredient used is an optional ingredient of the finished ice cream. Coloring, including artificial coloring, may be added.[5]

(b) The optional characterizing ingredients referred to in paragraph (a) of this section are:

(1) Ground spice, ground vanilla beans, infusion of coffee or tea, or any natural food flavoring.

(2) Artificial food flavoring.

(3) Chocolate or cocoa, which may be added as such or as a suspension in sirup, and which may contain disodium phosphate or sodium citrate in such quantity that the finished ice cream contains not more than 0.2 percent by weight of disodium phosphate or sodium citrate. For the purposes of this section, the term "cocoa" means one or any combination of two or more of the following: Cocoa, breakfast cocoa, low-fat cocoa, and the unpulverized residual material prepared by removing part of the fat from ground cacao nibs.

(4) Mature fruit or the juice of mature fruit, either of which may be fresh, frozen, canned, concentrated, or partially or wholly dried. The fruit may be whole, shredded, or comminuted; it may be sweetened, thickened with pectin or with one or more of the ingredients named in paragraph (f) (2) of this section, subject to the restriction on the total quantity of such substances in ice cream prescribed in that paragraph, and it may be acidulated with citric acid, ascorbic acid, or phosphoric acid. The fruit is prepared by the removal of pits, seeds, skins, and cores, where such removal is usual in preparing that kind of fruit for consumption as fresh fruit. In the case of fruit or fruit juice from which part of the water is removed, the substances contributing flavor volatilized during water removal may be condensed and reincorporated in the concentrated fruit or fruit juice. In the case of the citrus fruits the whole fruit, including the peel but excluding the seeds, may be used, and in the case of citrus juice or concentrated citrus juice, cold-pressed citrus oil may be added in an amount not exceeding that which would have been obtained if the peel from the whole fruit had been used. For the purposes of this section, the flesh of the coconut shall be considered a fruit.

(5) Nut meats, which may be roasted, cooked in an edible fat or oil, or preserved in sirup, and which may be salted.

(6) Malted milk.

(7) Confectionery. For the purposes of this section, the term "confectionery" means candy, cakes, cookies, and glacéed fruits.

(8) Properly prepared and cooked cereal.

(9) Distilled alcoholic beverage, including liqueurs or wine, in an amount not to exceed that required for flavoring the ice cream.

(c) The optional dairy ingredients referred to in paragraph (a) of this section are: Cream, dried cream, plastic cream (sometimes known as concentrated milk (fat), butter, butter oil, milk, concentrated milk, evaporated milk, sweetened condensed milk, superheated condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, condensed skim milk, superheated condensed skim milk, sweetened condensed skim milk, sweetened condensed part-skim milk, nonfat dry milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, skim milk that has been concentrated and from which part of the lactose has been removed by crystallization, skim milk in concentrated or dried form which has been modified by treating the

[5] Section 403(k) of the Federal Food, Drug, and Cosmetic Act grants label declaration exemption for artificial coloring in ice cream.

concentrated skim milk with calcium hydroxide and disodium phosphate, concentrated cheese whey, and dried cheese whey. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent, calculated as lactic acid. The term "milk" as used in this section means cow's milk. Any concentrated cheese whey and dried cheese whey used contribute not more than 25 percent by weight of the total nonfat milk solids content of the finished food. Dried cheese whey is uniformly light in color, free from brown and black scorched particles, and has an alkalinity of ash, not more than 225 milliliters 0.1*N* HCl per 100 grams, a bacterial count of not more than 50,000 per gram, and, as adjusted with water to a total solids content of 6.5 percent, a titratable acidity of not more han 0.16 percent, calculated as lactic acid. Concentrated cheese whey has an alkalinity of ash, not more than 115 milliliters 0.1*N* HCl per 100 grams, a bacterial count of not more than 50,000 per gram, and, as adjusted with water to a total solids content of 6.5 percent, a titratable acidity of not more than 0.18 percent, calculated as lactic acid. The modified skim milk, when adjusted with water to a total solids content of 9 percent is substantially free of lactic acid as determined by titration with 0.1*N* NaOH and it has a pH value in the range of 8.0 to 8.3.

(d) The optional sweetening ingredients referred to in paragraph (a) of this section are:

(1) Sugar (sucrose) or sugar sirup.

(2) Dextrose.

(3) Invert sugar (in paste or sirup form).

(4) Corn sirup, dried corn sirup, glucose sirup, dried glucose sirup.

(5) Maple sirup, maple sugar.

(6) Honey.

(7) Brown sugar.

(8) Malt sirup, maltose sirup, malt extract.

(9) Dried malt sirup, dried maltose sirup, dried malt extract.

(10) Refiner's sirup.

(11) Molasses (other than blackstrap).

(12) Lactose.

(13) Fructose N. F.

(e) The optional caseinates referred to in paragraph (a) of this section which may be added to ice cream mix containing not less than 20 percent total milk solids are: Casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate, and sodium caseinate. Caseinates may be added in liquid or dry form, but must be free of excess alkali.

(f) Other optional ingredients referred to in paragraph (a) of this section are:

(1) Liquid eggs, frozen eggs, dried eggs, egg yolks, frozen egg yolks, and dried egg yolks. Any egg ingredient used is added to the mix before it is pasteurized. The total weight of egg yolk solids in the finished ice cream from one or a combination of two or more such ingredients is less than the minimum prescribed for frozen custard by § 135.10 (1.4 percent).

(2) Agar-agar, algin (sodium alginate), calcium sulfate, gelatin, gum acacia, guar seed gum, gum karaya, locust bean gum, oat gum, gum tragacanth, carrageenan, salts of carrageenan, furcelleran, salts of furcelleran, lecithin, psyllium seed husk, sodium carboxymethylcellulose. The total weight of the solids of any such ingredient used singly or of any combination of two or more such ingredients used (including any such ingredient and pectin added separately to the fruit ingredient) is not more than 0.5 percent of the weight of the finished ice cream. Such ingredients may be added in admixture with dextrin, propylene glycol, or glycerin.

(3) Monoglycerides or diglycerides or both of fat-forming fatty acids. The total weight of such ingredients is not more than 0.2 percent of the weight of the finished ice cream. If the preparation used is one having a high proportion of monoglycerides (over 90 percent), it may be preblended with edible fat, but the amount of such fat does not exceed 20 percent by weight of the blend, and the total amount of the blend used does not exceed 0.2 percent of the weight of the finished ice cream.

(4) Polysorbate 65, polysorbate 80, or both (complying with the provisions of § 172.838 and § 172.840 of this chapter including the limit on either used separately or both used in combination of not more than 0.1 percent by weight of the finished frozen dessert).

(5) Propylene glycol alginate (complying with the provisions of § 172.858 of this chapter including the limit of not more than 0.5 percent by weight of the finished frozen dessert).

(6) Microcrystalline cellulose, in a quantity not to exceed 1.5 percent by weight of the finished frozen dessert.

(7) When one or more of the optional thickening ingredients in paragraph (f) (2) or (5) of this section are used, dioctyl sodium sulfosuccinate complying with the requirements of § 172.810 of this chapter may be used in a quantity not in excess of 0.5 percent by weight of such ingredients.

(8) (i) Sodium citrate, disodium phosphate, tetrasodium pyrophosphate, sodium hexametaphosphate, or any combination of two or more of these; but the total quantity of the solids of such ingredients (exclusive of any disodium phosphate or sodium citrate present in chocolate or cocoa, as permitted by paragraph (b) (3) of this section) is not more than 0.2 percent by weight of the finished ice cream.

(ii) Calcium oxide, magnesium oxide, calcium hydroxide, magnesium hydroxide, calcium carbonate, magnesium carbonate, or any combination of two or more of these; but the total quantity of the solids of such ingredients is not more than 0.04 percent of the weight of the finished ice cream.

(g) (1) The name of the food is "ice cream".

(2) (i) If the food contains no artificial flavor, the name on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla", in letters not less than one-half the height of the letters used in the words "ice cream".

(ii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the natural flavor predominates, the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor, in letters not less than one-half the height of the letters used in the words "ice cream", followed by the word "flavored", in letters not less than one-half of the height of the letters in the name of the characterizing flavor, e.g., "VANILLA flavored", or "PEACH flavored", or "VANILLA flavored and STRAWBERRY flavored".

(iii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the artificial flavor predominates, or if artificial flavor is used alone, the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor, in letters not less than one-half the height of the letters used in the words "ice cream", preceded by "artificial" or "artificially flavored", in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "artificial VANILLA", or "artificially flavored STRAWBERRY" or "artificially flavored VANILLA and artificially flavored STRAWBERRY".

(3) (i) If the food is subject to the requirements of paragraph (g) (2) (ii) of this section or if it contains any artificial flavor not simulating the characterizing flavor, the label shall also bear the words "artificial flavor added" or "artificial _____ flavor added", the blank being filled with the common name of the flavor simulated by the artificial flavor in letters of the same size and prominence as the words that precede and follow it.

(ii) When the optional ingredient microcrystalline cellulose specified in paragraph (f) (6) of this section is used, the label shall bear the statement "microcrystalline cellulose added" or "with microcrystalline cellulose".

(iii) When two or more of the optional ingredients specified in paragraphs (b) (2) and (f) (6) of this section are used, such words may be combined; for example, "microcrystalline cellulose and artificial flavor added".

(iv) Wherever the name of the characterizing flavor appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph (g) (3) shall immediately and conspicuously precede or follow such name, in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1 pint, not less than 8-point on packages containing at least

1 pint but less than one-half gallon, not less than 10-point on packages containing at least one-half gallon but less than 1 gallon, and not less than 12-point on packages containing 1 gallon or over; *Provided, however,* That where the characterizing flavor and a trade mark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trade mark or brand, may intervene if the required words are in such relationship with the trade mark or brand as to be clearly related to the characterizing flavor: *And provided further,* That if the finished product contains more than one flavor of ice cream subject to the requirements of this paragraph (g)(3), the statements required by this paragraph (g)(3) need appear only once in each statement of characterizing flavors present in such ice cream, e.g., "VANILLA flavored, CHOCOLATE and STRAWBERRY flavored, artificial flavors added".

(4) If the food contains both a natural characterizing flavor and an artificial flavor simulating the characterizing flavor, any reference to the natural characterizing flavor shall, except as otherwise authorized by this paragraph (g), be accompanied by a reference to the artificial flavor, displayed with substantially equal prominence, e.g., "strawberry and artificial strawberry flavor".

(5) An artificial flavor simulating the characterizing flavor shall be deemed to predominate:

(i) In the case of vanilla beans or vanilla extract used in combination with vanillin if the amount of vanillin used is greater than 1 ounce per unit of vanilla constituent, as that term is defined in § 169.3(c) of this chapter.

(ii) In the case of fruit or fruit juice used in combination with artificial fruit flavor, if the quantity of the fruit or fruit juice used is such that, in relation to the weight of the finished ice cream, the weight of the fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content), is less than 2 percent in the case of citrus ice cream, 6 percent in the case of berry or cherry ice cream, and 10 percent in the case of ice cream prepared with other fruits.

(iii) In the case of nut meats used in combination with artificial nut flavor, if the quantity of nut meats used in such that, in relation to the finished ice cream, the weight of the nut meats is less than 2 percent.

(iv) In the case of two or more fruits or fruit juices, or nut meats, or both, used in combination with artificial flavors simulating the natural flavors and dispersed throughout the food, if the quantity of any fruit or fruit juice or nut meat is less than one-half the applicable percentage specified in paragraph (g)(5)(ii) or (iii) of this section. For example, if a combination ice cream contains less than 5 percent of bananas and less than 1 percent of almonds it would be "Artificially flavored banana-almond ice cream". However, if it contains more than 5 percent of bananas and more than 1 percent of almonds it would be "Banana-almond flavored ice cream".

(6) If two or more flavors of ice cream are distinctively combined in one package, e.g., "Neapolitan" ice cream, the applicable provisions of this paragraph (g) shall govern each flavor of ice cream comprising the combination.

§ 135.40 Ice milk.

Ice milk is the food prepared from the same ingredients and in the same manner prescribed in § 135.30 for ice cream and complies with all the provisions of § 135.30 (including the requirements for label statement of optional ingredients), except that:

(a) Its content of milk fat is more than 2 percent but not more than 7 percent.

(b) Its content of total milk solids is not less than 11 percent.

(c) Caseinates may be added when the content of total milk solids is not less than 11 percent.

(d) The provision for reduction in milk fat and total milk solids from the addition of bulky ingredients in § 135.30(a) does not apply.

(e) The quantity of food solids per gallon is not less than 1.3 pounds; except that when the optional ingredient microcrystalline cellulose specified in § 135.30(f)(6) is used the quantity of food solids per gallon is not less than 1.3 pounds, exclusive of the weight of the microcrystalline cellulose.

(f) When any artificial coloring is used in ice milk, directly or as a component of any other ingredient, the label shall bear the statement "artificially colored", "artificial coloring added", "with added artificial color", or "_____, an artificial color added", the blank being filled in with the common or usual name of the artificial color; or in lieu thereof, in case the artificial color is a component of another ingredient, "_____ artificially colored".

(g) The name of the food is "ice milk".

(h) If both artificial color and artificial flavoring are used, the label statements may be combined.

§ 135.50 Mellorine.

(a) *Description.* (1) Mellorine is a food produced by freezing, while stirring, a pasteurized mix consisting of safe and suitable ingredients including, but not limited to, milk-derived nonfat solids and animal or vegetable fat, or both, only part of which may be milkfat. Mellorine is sweetened with nutritive carbohydrate sweetener and is characterized by the addition of flavoring ingredients.

(2) Mellorine contains not less than 1.6 pounds of total solids to the gallon, and weighs not less than 4.5 pounds to the gallon. Mellorine contains not less than 6 percent fat and 2.7 percent protein by weight of the food, exclusive of the weight of any bulky flavoring ingredients used. In no case shall the fat content of the finished food be less than 4.8 percent or the protein content be less than 2.2 percent. The protein to meet the minimum protein requirements shall be provided by milk solids not fat and/or other milk-derived ingredients, and shall have a protein efficiency ratio (PER) not less than that of whole milk protein (120 percent of casein as determined by the method prescribed in paragraph (d)(3) of this section).

(3) When calculating the minimum amount of milkfat and protein required in the finished food, the solids of chocolate or cocoa used shall be considered a bulky flavoring ingredient. In order to make allowance for additional sweetening ingredients needed when certain bulky ingredients are used, the weight of chocolate or cocoa solids used may be multiplied by 2.5; the weight of fruit or nuts used may be multiplied by 1.4; and the weight of partially or wholly dried fruits or fruit juices may be multiplied by appropriate factors to obtain the original weights before drying and this weight may be multiplied by 1.4.

(b) *Fortification.* Vitamin A is present in a quantity which will ensure that 40 international units (IU) are available for each gram of fat in mellorine, within limits of good manufacturing practice.

(c) *Definitions.* For the purposes of this section a pasteurized mix is one every particle of which has been heated in properly operated equipment to one of the temperatures specified in the table of this paragraph and held continuously at or above that temperature for the specified time (or other time/temperature relationship which has been demonstrated to be equivalent thereto in microbial destruction):

Temperature:	*Time*
155° F.	30 minutes
175° F.	25 seconds

(d) *Methods of analysis.* Fat and protein content, and the PER shall be determined by the methods contained in the "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th ed., 1970.[3]

(1) Fat content shall be determined by the method: "Fat, Roese-Gottlieb Method—Official Final Action," section 16.226.

(2) Protein content shall be determined by one of the following methods: "Nitrogen—Official Final Action," Kjeldahl Method, section 16.226, or Dye Binding Method, section 16.227.

(3) PER shall be determined by the method: "Biological Evaluation of Protein Quality—Official Final Action" sections 39.166–39.170.

(e) *Nomenclature.* The name of the food is "mellorine". The name of the food on the label shall be accompanied by a declaration indicating the presence of characterizing flavoring in the same manner as is specified in § 135.30(g).

(f) *Label declaration.* The common or usual name of each of the ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that sources of milkfat or milk solids not fat may be declared, in descending order of predominance, either by the use of all the terms "water, milkfat, and nonfat milk solids",

or alternatively as permitted in § 101.4 of this chapter.

NOTE: § 135.50 (formerly § 20.8) was stayed in its entirety at 40 FR 59725, Dec. 30, 1975.

§ 135.65 Nonfruit sherbets.

(a) Nonfruit sherbets are the foods each of which is prepared by freezing, while stirring, a mix composed of one or more of the optional characterizing ingredients specified in paragraph (b) of this section and one or more of the optional dairy ingredients specified in paragraph (c) of this section, sweetened with one or more of the optional sweetening ingredients specified in paragraph (d) of this section. One or more of the optional ingredients specified in paragraph (e) of this section may be used, subject to the conditions hereinafter set forth. The mix of combined dairy ingredients, with or without other ingredients, is pasteurized. The mix, with or without added water, may be seasoned with salt and may be homogenized. The optional dairy ingredients used and the content of milk fat and nonfat milk solids therein are such that the weight of milk fat is not less than 1 percent and not more than 2 percent and the weight of total milk solids is not less than 2 percent and not more than 5 percent of the weight of the finished nonfruit sherbets. The optional caseinates specified in paragraph (e) (7) of this section are not deemed to be milk solids. The finished nonfruit sherbet weighs not less than 6 pounds to the gallon; except that when the optional ingredient microcrystalline cellulose specified in paragraph (e) (9) of this section is used, the finished nonfruit sherbet weighs not less than 6 pounds to the gallon, exclusive of the weight of the microcrystalline cellulose.

(b) The optional characterizing ingredients referred to in paragraph (a) of this section are:

(1) Ground spice or infusion of coffee or tea.

(2) Chocolate or cocoa, including sirup.

(3) Confectionery.

(4) Distilled alcoholic beverage, including liqueurs or wine, in an amount not to exceed that required for flavoring the sherbet.

(5) Any natural or artificial food flavoring (except any having a characteristic fruit or fruitlike flavor).

(c) The optional dairy ingredients referred to in paragraph (a) of this section are: Cream, dried cream, plastic cream (sometimes known as concentrated milk fat), butter, butter oil, milk, concentrated milk, evaporated milk, superheated condensed milk, sweetened condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, condensed skim milk, superheated condensed skim milk, sweetened condensed skim milk, sweetened condensed part-skim milk, nonfat dry milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, skim milk that has been concentrated and from which part of the lactose has been removed by crystallization, concentrated cheese whey, and dried cheese whey. Water may be added or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent calculated as lactic acid. The term "milk" as used in this section means cow's milk. Dried cheese whey is uniformly light in color, free from brown and black scorched particles, and has an alkalinity of ash not more than 225 milliliters 0.1*N* HCl per 100 grams, a bacterial count of not more than 50,000 per gram, and, as adjusted with water to a total solids content of 6.5 percent, a titratable acidity of not more than 0.16 percent calculated as lactic acid. Concentrated cheese whey has an alkalinity of ash not more than 115 milliliters of 0.1*N* HCl per 100 grams, a bacterial count of not more than 50,000 per gram, and, as adjusted with water to a total solids content of 6.5 percent, a titratable acidity of not more than 0.16 percent calculated as lactic acid.

(d) The optional sweetening ingredients referred to in paragraph (a) of this section are: Sugar (sucrose), dextrose, invert sugar (paste or sirup), glucose sirup, dried glucose sirup, corn sirup, dried corn sirup, malt sirup, malt extract, dried malt sirup, dried malt extract, maltose sirup, dried maltose sirup.

(e) Other optional ingredients referred to in paragraph (a) of this section are:

(1) Liquid eggs, frozen eggs, dried eggs, egg yolks, frozen yolks, dried yolks; but the weight of egg yolk solids therein is less than 0.5 percent of the weight of the finished nonfruit sherbet.

(2) Agar-agar, algin (sodium alginate), calcium sulfate, egg white, gelatin, gum acacia, guar seed gum, gum karaya, locust bean gum, oat gum, gum tragacanth, hydroxypropyl methylcellulose, carrageenan, salts of carrageenan, furcelleran, salts of furcelleran, lecithin, pectin, psyllium seed husk, sodium carboxymethylcellulose. The total weight of the solids of any such ingredient used singly or of any combination of two or more such ingredients used is not more than 0.5 percent of the weight of the finished, nonfruit sherbet. Such ingredients may be added in admixture with dextrin, propylene glycol, or glycerin.

(3) Monoglycerides or diglycerides or both of fat-forming fatty acids. The total weight of such ingredients is not more than 0.2 percent of the weight of the finished nonfruit sherbet. If the preparation used is one having a high proportion of monoglycerides (over 90 percent), it may be preblended with edible fat, but the amount of such fat does not exceed 20 percent by weight of the blend and the total amount of the blend used does not exceed 0.2 percent of the weight of the finished nonfruit sherbet.

(4) Polysorbate 65, polysorbate 80, or both, (complying with the provisions of §§ 172.838 and 172.840 of this chapter including the limit on either used separately or both used in combination of not more than 0.1 percent by weight of the finished frozen dessert).

(5) Propylene glycol alginate (complying with the provisions of § 172.858 of this chapter including the limit of not more than 0.5 percent by weight of the finished frozen dessert).

(6) Citric acid, tartaric acid, malic acid, lactic acid, ascorbic acid, phosphoric acid, or any combination of two or more of these in such quantity as seasons the finished food.

(7) Casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate, sodium caseinate.

(8) Coloring, including artificial coloring.

(9) Microcrystalline cellulose, in a quantity not to exceed 0.5 percent of the weight of the finished nonfruit sherbet.

(10) When one or more of the optional thickening ingredients in paragraph (e) (2) or (5) of this section are used, dioctyl sodium sulfosuccinate complying with the requirements of § 172.810 of this chapter may be used in a quantity not in excess of 0.5 percent by weight of such ingredients.

(f) Except as provided for in paragraph (g) of this section, the name of each such nonfruit sherbet is "_____sherbet", the blank being filled in with the common or usual name or names of the characterizing flavor or flavors; for example, "peppermint".

(g) If the characterizing flavor used is vanilla, the name of the food is "_____sherbet", the blank being filled in as specified by § 135.30(g) (2) and (5) (i).

(h) When the optional ingredients artificial flavoring, artificial coloring, or microcrystalline cellulose are used in nonfruit sherbet, they shall be named on the label as follows:

(1) If the flavoring ingredient or ingredients consists exclusively of artificial flavoring, the label designation shall be "artificially flavored".

(2) If the flavoring ingredients are a combination of natural and artificial flavors, the label designation shall be "artificial and natural flavoring added".

(3) The label shall designate artificial coloring by the statement "artificially colored", "artificial coloring added", "with added artificial coloring", or "_____, an artificial color added", the blank being filled in with the name of the artificial coloring used.

(4) When the optional ingredient microcrystalline cellulose is used, the label shall bear the statement "microcrystalline cellulose added" or "with added microcrystalline cellulose".

(i) Wherever there appears on the label any representation as to the characterizing flavor or flavors of the food and such flavor or flavors consist in whole or in part of artificial flavoring, the statement required by paragraph (h) (1) or (2) of this section, as appropriate, shall immediately and conspicuously precede or follow such representation, without intervening written, printed, or graphic matter (except that the word

"sherbet" may intervene) in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1 pint, not less than 8-point on packages containing at least 1 pint but less than one-half gallon, not less than 10-point on packages containing at least one-half gallon but less than 1 gallon, and not less than 12-point on packages containing 1 gallon or over.

(j) Except as specified in paragraph (i) of this section, the statements required by paragraph (h) of this section shall be set forth on the principal display panel or panels of the label with such prominence and conspicuousness as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

§ 135.70 Nonfruit water ices.

(a) Nonfruit water ices are the foods each of which is prepared by freezing, while stirring, a mix composed of one or more of the optional characterizing ingredients specified in paragraph (b) of this section, sweetened with one or more of the optional sweetening ingredients specified in paragraph (c) of this section. One or more of the optional ingredients specified in paragraph (d) of this section may be used, subject to the conditions hereinafter set forth. The mix, with or without added water, may be seasoned with salt and may be homogenized. The finished nonfruit water ice weighs not less than 6 pounds to the gallon.

(b) The optional characterizing ingredients referred to in paragraph (a) of this section are:

(1) Ground spice or infusion of coffee or tea.

(2) Chocolate or cocoa, including sirup.

(3) Confectionery.

(4) Distilled alcoholic beverage, including liqueurs or wine, in an amount not to exceed that required for flavoring the water ice.

(5) Any natural or artificial food flavoring (except any having a characteristic fruit or fruit-like flavor).

(c) The optional sweetening ingredients referred to in paragraph (a) of this section are: Sugar (sucrose), dextrose, invert sugar (paste or sirup), glucose sirup, dried glucose sirup, corn sirup, dried corn sirup, malt sirup, malt extract, dried malt sirup, dried malt extract, maltose sirup, dried maltose sirup.

(d) Other optional ingredients referred to in paragraph (a) of this section are:

(1) (i) Agar-agar, algin (sodium alginate), egg white, gelatin, gum acacia, guar seed gum, gum karaya, locust bean gum, oat gum, gum tragacanth, hydroxypropyl methylcellulose, carrageenan, salts of carrageenan, furcelleran, salts of furcelleran, propylene glycol alginate, pectin, psyllium seed husk, sodium carboxymethylcellulose. The total weight of the solids of any such ingredient used singly, or of any combination of two or more such ingredients used, is not more than 0.5 percent of the weight of the finished nonfruit water ice. Such ingredients may be added in admixture with dextrin, propylene glycol, or glycerin.

(ii) When one or more of the optional thickening ingredients in paragraph (d) (1) (i) of this section are used, dioctyl sodium sulfosuccinate complying with the requirements of § 172.810 of this chapter may be used in a quantity not in excess of 0.5 percent by weight of such ingredients.

(2) Citric acid, tartaric acid, malic acid, lactic acid, ascorbic acid, phosphoric acid, or any combination of two or more of these in such quantity as seasons the finished food.

(3) Coloring, including artificial coloring.

(e) Except as provided for in paragraph (f) of this section, the name of each such nonfruit water ice is "_____ ice", the blank being filled in with the common or usual name or names of the characterizing flavor or flavors; for example, "peppermint".

(f) If the characterizing flavor used is vanilla, the name of the food is "_____ ice", the blank being filled in as specified by § 135.30(g) (2) and (5) (i).

(g) When the optional ingredients artificial flavoring or artificial coloring are used in nonfruit water ice, they shall be named on the label as follows:

(1) If the flavoring ingredient or ingredients consist exclusively of artificial flavoring, the label designation shall be "artificially flavored".

(2) If the flavoring ingredients used are a combination of natural and artificial flavors, the label designation shall be "artificial and natural flavoring added".

(3) The label shall designate artificial coloring by the statement "artificially colored", "artificial coloring added", "with added artificial coloring", or "_____ an artificial color added", the blank being filled in with the name of the artificial coloring used.

(h) Wherever there appears on the label any representation as to the characterizing flavor or flavors of the food and such flavor or flavors consist in whole or in part of artificial flavoring, the statement required by paragraph (g) (1) or (2) of this section, as appropriate, shall immediately and conspicuously precede or follow such representation, without intervening written, printed, or graphic matter (except that the word "ice" may intervene) in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1 pint, not less than 8-point on packages containing at least 1 pint but less than one-half gallon, not less than 10-point on packages containing at least one-half gallon but less than 1 gallon, and not less than 12-point on packages containing 1 gallon or over.

(i) Except as specified in paragraph (h) of this section, the statements required by paragraph (g) of this section shall be set forth on the principal display panel or panels or the label with such prominence and conspicuousness as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

§ 135.90 Water ices.

(a) Water ices are the foods each of which is prepared by freezing, while stirring, a mix composed of one or more of the optional characterizing fruit ingredients specified in paragraph (b) of this section, sweetened with one or more of the optional sweetening ingredients specified in paragraph (c) of this section. One or more of the optional ingredients specified in paragraph (d) of this section may be used, subject to the conditions hereinafter set forth. The titratable acidity of the finished water ice, calculated as lactic acid, is not less than 0.35 percent. The mix, with or without added water, may be seasoned with salt, and may be homogenized. The finished water ice weighs not less than 6 pounds to the gallon.

(b) The optional fruit ingredients referred to in paragraph (a) of this section are any mature fruit or the juice of any mature fruit. The fruit or fruit juice used may be fresh, frozen, canned, concentrated, or partially or wholly dried. The fruit may be thickened with pectin or other of the optional ingredients named in paragraph (d) (1) of this section subject to the restriction on the total quantity of such substances in water ices prescribed in that paragraph. The fruit is prepared by the removal of pits, seeds, skins, and cores where such removal is usual in preparing that kind of fruit for consumption as fresh fruit. The fruit may be screened, crushed, or otherwise comminuted. It may be acidulated with citric acid, ascorbic acid, or phosphoric acid. In the case of fruit or fruit juices from which part of the water is removed, substances contributing flavor volatilized during water removal may be condensed and reincorporated in the concentrated fruit or fruit juice. In the case of citrus fruits, the whole fruit, including the peel but excluding the seeds, may be used, and in the case of citrus juice or concentrated citrus juices, cold-pressed citrus oil may be added thereto in an amount not exceeding that which would have been obtained if the whole fruit had been used. The quantity of fruit ingredients used is such that in relation to the weight of the finished water ice, the weight of fruit or fruit juice as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content) is not less than 2 percent in the case of citrus ices, 6 percent in the case of berry ices, and 10 percent in the case of ices prepared with other fruits.

(c) The optional sweetening ingredients referred to in paragraph (a) of this section are: Sugar (sucrose), dextrose, invert sugar (paste or sirup), glucose sirup, dried glucose sirup, corn sirup, dried corn sirup, malt sirup, malt extract, dried malt sirup, dried malt extract, maltose sirup, dried maltose sirup.

(d) Other optional ingredients referred to in paragraph (a) of this section are:

(1) (i) Agar-agar, algin, (sodium alginate), egg white, gelatin, gum acacia, guar seed gum, gum karaya, locust bean gum, oat gum, gum tragacanth, hydroxypropyl methylcellulose, carrageenan, salts of carrageenan, furcelleran, salts of furcelleran, propylene glycol alginate, pectin, psyllium seed husk, sodium carboxymethylcellulose. The total weight of the solids of any such ingredient used singly, or of any combination of two or more such ingredients used (including any such ingredient added separately to the fruit ingredient), is not more than 0.5 percent of the weight of the finished water ice. Such ingredients may be added in admixture with dextrin, propylene glycol, or glycerin.

(ii) When one or more of the optional thickening ingredients in paragraph (d) (1) (i) of this section are used, dioctyl sodium sulfosuccinate complying with the requirements of § 172.810 of this chapter may be used in a quantity not in excess of 0.5 percent by weight of such ingredients.

(2) Citric acid, tartaric acid, malic acid, lactic acid, ascorbic acid, phosphoric acid, or any combination of two or more of these in such quantity as seasons the finished food.

(3) Any natural flavoring.

(4) Any artificial flavoring.

(5) Coloring, including artificial coloring.

(e) The name of each such water ice is "_____ ice", the blank being filled in with the common name of the fruit or fruits from which the fruit ingredient used is obtained. When the names of two or more fruits are included, such names shall appear in the order of predominance, if any, by weight of the respective fruit ingredients used.

(f) When the optional ingredients artificial coloring and artificial flavoring are used in water ices they shall be named on the labels as follows:

(1) The label shall designate artificial coloring by the statement "artificially colored", "artificial coloring added", "with added artificial coloring", or "_____, an artificial color added", the blank being filled in with the name of the artificial coloring used.

(2) The label shall designate artificial flavoring by the statement "artificially flavored", "artificial flavoring added", "with added artificial flavoring", or "_____, an artificial flavor added", the blank being filled in with the name of the the artificial flavoring used.

Label statements may be combined, as for example, "flavoring and artificial coloring added".

(g) Where one or more of the optional ingredients artificial coloring or artificial flavoring are used and there appears on the labeling any representation as to the fruit or fruits in the ice, such representation shall be immediately and conspicuously accompanied by appropriate label statements as prescribed in paragraph (f) of this section, showing the optional ingredients used.

(h) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements set out in this section showing the optional ingredients used shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

PART 136—BAKERY PRODUCTS

Subpart A—General Provisions

Sec.

136.3 Definitions.

Subpart B—Requirements for Specific Standardized Bakery Products

136.110 Bread, rolls, and buns.
136.115 Enriched bread, rolls, and buns.
136.130 Milk bread, rolls, and buns.
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136.180 Whole wheat bread, rolls, and buns.

AUTHORITY: Secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e)).

Subpart A—General Provisions

§ 136.3 Definitions.

For purposes of this part, the following definitions apply:

(a) The word "bread" when used in the name of the food means the unit weighs one-half pound or more after cooling.

(b) The words "rolls" and "buns" when used in the name of the food mean the unit weighs less than one-half pound after cooling.

Subpart B—Requirements for Specific Standardized Bakery Products

§ 136.110 Bread, rolls, and buns.

(a) Bread, white bread, and rolls, white rolls, or buns, and white buns are the foods produced by baking mixed yeast-leavened dough prepared from one or more of the farinaceous ingredients listed in paragraph (c) (1) of this section and one or more of the moistening ingredients listed in paragraph (c) (2), (6), (7), and (8) of this section and one or more of the leavening agents provided for by paragraph (c) (3) of this section. The food may contain additional ingredients as provided for by paragraph (c) of this section. Each of the finished foods contains not less than 62 percent total solids as determined by the method prescribed in paragraph (d) of this section.

(b) All ingredients from which the food is fabricated shall be safe and suitable.

(c) The following optional ingredients are provided for:

(1) Flour, bromated flour, phosphated flour, or a combination of two or more of these. The potassium bromate in any bromated flour used and the monocalcium phosphate in any phosphated flour used are deemed to be additional optional ingredients in the bread, rolls, or buns. All ingredients in any flour, bromated flour, or phosphated flour used are deemed to be optional ingredients of the bread, rolls, or buns prepared therefrom.

(2) Water.

(3) Yeast—any type which produces the necessary leavening effect.

(4) Salt.

(5) Shortening, in which or in conjunction with which may be used one or any combination of two or more of the following:

(i) Lecithin, hydroxylated lecithin complying with the provisions of Part 172 of this chapter, either of which may include related phosphatides derived from the corn oil or soybean oil from which such ingredients were obtained.

(ii) Mono- and diglycerides of fat-forming fatty acids, diacetyl tartaric acid esters of mono- and diglycerides of fat-forming fatty acids, propylene glycol mono- and diesters of fat-forming fatty acids complying with the provisions of Part 172 of this chapter, or a combination of two or more of these. The total quantity of these ingredients whether used alone or in combination does not exceed 0.5 part for each 100 parts by weight of flour used.

(6) Milk and/or other dairy products in such quantity and composition as not to meet the requirements for milk and/or other dairy products prescribed for milk bread by § 136.130. Whenever nonfat milk solids in any form are used, carrageenan or salts of carrageenan complying with the provisions of Part 172 of this chapter may be used in a quantity not in excess of 0.8 percent by weight of such nonfat milk solids.

(7) Egg products.

(8) Nutritive carbohydrate sweeteners.

(9) Enzyme active preparations.

(10) Lactic-acid-producing bacteria.

(11) Nonwheat flours, nonwheat meals, nonwheat grits, wheat and nonwheat starches, any of which may be wholly or in part dextrinized, dextrinized wheat flour, or any combination of 2 or more of these, if the total quantity is not more than 3 parts for each 100 parts by weight of flour used.

(12) Ground dehulled soybeans which may be heat-treated, and from which oil may be removed, but which retain enzymatic activity, if the quantity is not more than 0.5 part for each 100 parts by weight of flour used.

(13) Yeast nutrients and calcium salts, if the total quantity of such ingredients, with the exception of monocalcium phosphate and calcium propionate, is not more than 0.25 part for each 100 parts by weight of flour used. The quantity of monocalcium phosphate, including any quantity in the flour used, is not more than 0.75 part for each 100 parts by weight of flour used. Any calcium propionate used as a preservative in bread, rolls, or buns is not subject to the limitation prescribed in this paragraph.

(14) (i) Potassium bromate, calcium bromate, potassium iodate, calcium iodate, calcium peroxide, or any combination of 2 or more of these if the total quantity, including the potassium bromate in any bromated flour used, is not more than 0.0075 part for each 100 parts by weight of flour used.

(ii) Azodicarbonamide, if the total quantity, including any quantity in the flour used, is not more than 0.0045 part for each 100 parts by weight of flour used.

(15) Dough strengtheners and other dough conditioners not specifically listed in this paragraph, if the total quantities of such ingredients or combination is not more than 0.5 part for each 100 parts by weight of flour used.

(16) Spices, spice oil, and spice extract which do not impart a color simulating that of egg to the finished food.

(17) Coloring may not be added as such or as part of another ingredient except that which may be present in butter if the intensity of the butter color does not exceed "medium high" (MH) when viewed under diffused light (7400 Kelvin) against the Munsell Butter Color Comparator. The MH designation corresponds to the Munsell renotation of 3.8Y 7.9/7.6.

(18) Other ingredients that do not change the basic identity or adversely affect the physical and nutritional characteristics of the bread.

(d) Total solids are determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. 1975, sec. 14.083(a),[2] except that if the baked unit weighs 1 pound or more, one entire unit is used for the determination; if the baked unit weighs less than 1 pound, enough units to weigh 1 pound or more are used.

(e)(1) The name of the food is "bread", "white bread", "rolls", "white rolls", "buns", "white buns", as applicable. When the food contains not less than 2.56 percent by weight of whole egg solids, the name of the food may be "egg bread", "egg rolls", or "egg buns", as applicable, accompanied by the statement "Contains ____ medium-sized egg(s) per pound" in the manner prescribed by § 102.5(c)(3) of this chapter, the blank to be filled in with the number which represents the whole egg content of the food expressed to the nearest one-fifth egg but not greater than the amount actually present. For the purpose of this regulation, whole egg solids are the edible contents of eggs calculated on a moisture-free basis and exclusive of any nonegg solids which may be present in standardized and other commercial egg products. One medium-sized egg is equivalent to 0.41 ounce of whole egg solids.

(2) When the label bears any representation, other than in the ingredient listing, of the presence of egg in the food, e.g., the word egg or any phonetic equivalent spelling of the word egg, or a picture of an egg, the food shall contain not less than 2.56 percent of whole egg solids.

(f) All ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

NOTE.—The confirmation of effective date for § 136.110 (formerly § 17.10) published in the FEDERAL REGISTER of October 15, 1976 (41 FR 45540) stated that the following provisions are stayed pending full review of the objections and requests for hearing:

a. Paragraph (c)(5)(i) as it pertains to egg bread, egg rolls, and egg buns.

b. Paragraph (c)(5)(ii): Pending resolution of the issue, the requirements of § 136.110(a)(1)(ii) of the superseded standard will apply. That standard reads as follows:

(ii) Mono- and diglycerides of fat-forming fatty acids, diacetyl tartaric acid esters of mono- and diglycerides of fat-forming fatty acids, propylene glycol mono- and diesters of fat-forming fatty acids complying with the provisions of § 172.856 (formerly § 121.1113) of this chapter, or a combination of two or more of these. The total weight of these ingredients used does not exceed 20 percent by weight of the combination of such ingredients and the shortening, and the total amount of monoglyceride, diacetyl tartaric acid ester of monoglyceride, and propylene glycol monoester does not exceed 8 percent by weight of the combination; but if purified or concentrated monoglyceride alone is used, the amount does not exceed 10 percent by weight of the combination.

c. Paragraph (c)(16) as it pertains to the use of spices, spice oil, or spice extract that imparts a color simulating that of egg to a standardized bakery product not represented on the label as containing egg or egg product and not purporting to contain egg or egg product.

d. Paragraph (c)(17), to include that portion that reads "except that which may be present in butter if the intensity of the butter color does not exceed 'medium high' (MH) when viewed under diffused light (7400 Kelvin) against the Munsell Butter Color Comparator. The MH designation corresponds to the Munsell re-notation of 3.8Y 7.9/7.6." Pending resolution of the issue, coloring may not be added as such or as part of another ingredient.

e. Paragraph (e) as it pertains to the use of the word "egg" in the name of the food.

§ 136.115 Enriched bread, rolls, and buns.

(a) Each of the foods enriched bread, enriched rolls, and enriched buns conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for bread, rolls or buns by § 136.110, except that:

(1) Each such food contains in each pound 1.8 milligrams of thiamine, 1.1 milligrams of riboflavin, 15 milligrams of niacin, and 25 milligrams of iron.

NOTE.—By an order published in the FEDERAL REGISTER of February 11, 1974 (39 FR 5188), concerning nutritional requirements for standardized enriched bakery products, the requirement that the food contain 25 milligrams of iron per pound was stayed. Accordingly, the requirement for iron reverts to not less than 8.0 milligrams and not more than 12.5 milligrams per pound pending resolution of the issue of the level of iron enrichment that was the subject of a hearing conducted in April 1974.

(2) Each such food may contain added calcium in such quantity that the total calcium content is 600 milligrams per pound. If insufficient calcium is added to meet the 600-milligram level per pound of the finished food, no claim may be made on the label for calcium as a nutrient except as a part of nutrition labeling.

(3) The requirements of paragraph (a)(1) and (2) of this section will be deemed to have been met if reasonable overages of the vitamins and minerals, within the limits of good manufacturing practice, are present to ensure that the required levels of the vitamins and minerals are maintained throughout the expected shelf life of the food under customary conditions of distribution and storage. The quantitative content of the following vitamins shall be calculated in terms of the following chemically identifiable reference forms:

Vitamin	Reference form		
	Name	Empirical formula	Molecular weight
Thiamine	Thiamine chloride hydrochloride.	$C_{12}H_{17}ClN_4OS \cdot HCl$	337.28
Riboflavin	Riboflavin	$C_{17}H_{20}N_4O_6$	376.37
Niacin	Niacin	$C_6H_5NO_2$	123.11

NOTE.—Pending resolution of the issue which was the subject of the hearing referred to in the note in par. (a)(1) of this section, the provision relating to the overages of vitamins and minerals does not apply to iron.

(4) Each such food may also contain wheat germ or partly defatted wheat germ, but the total quantity thereof, including any wheat germ or partly defatted wheat germ in any enriched flour used, shall not be more than 5 percent of the flour ingredient.

(5) Enriched flour may be used, in whole or in part, instead of flour. As used in this section, the term "enriched flour" includes enriched bromated flour.

(6) The limitation prescribed by § 136.110(c)(6) on the quantity and composition of milk and/or other dairy products does not apply.

(7) The vitamins and minerals added to the food for enrichment purposes may be supplied by any safe and suitable substances. Niacin equivalents as derived from tryptophan content shall not be used in determining total niacin content.

(b) The name of the food is "enriched bread", "enriched rolls", or "enriched buns", as applicable. When the food contains not less than 2.56 percent by weight of whole egg solids, the name of the food may be "enriched egg bread", "enriched egg rolls", or "enriched egg buns", as applicable, accompanied by the statement "Contains ____ medium-sized egg(s) per pound" in the manner prescribed by § 102.5(c)(3) of this chapter, the blank to be filled in with the number which represents the whole egg content of the food expressed to the nearest one-fifth egg but not greater than the amount actually present. For the purpose of this regulation, whole egg solids are the edible contents of eggs calculated on a moisture-free basis and exclusive of any non-egg solids which may be present in standardized and other commercial egg products. One medium-sized egg is equivalent to 0.41 ounce of whole egg solids. When the food complies with the requirements for milk and/or other dairy products content in § 136.130 for milk bread, the name of the food may be "enriched milk bread", "enriched milk rolls", or "enriched milk buns", as applicable. When the food complies with the requirements for both enriched egg bread and enriched milk bread in this section, the name of the food may be "enriched milk and egg bread", "enriched milk and egg rolls", or "enriched

milk and egg buns", as applicable accompanied by the statement "Contains ____ medium-sized egg(s) per pound" in the manner prescribed by § 102.5(c)(3) of this chapter, the blank to be filled in with the number which represents the whole egg content of the food expressed to the nearest one-fifth egg but no greater than the amount actually present. For purposes of this regulation, whole egg solids are the edible contents of eggs calculated on a moisture-free basis and exclusive of any non-egg solids which may be present in standardized or other commercial egg products. One medium-sized egg is equivalent to 0.41 ounce of whole egg solids.

NOTE.—The confirmation of effective date for § 136.115 (formerly § 17.20) published in the FEDERAL REGISTER of October 15, 1976 (41 FR 45540) stated that § 136.115(b), as it pertains to the use of the word "egg" in the name of the food, is stayed pending full review of the objections and requests for hearing.

§ 136.130 Milk bread, rolls, and buns.

(a) Each of the foods milk bread, milk rolls, and milk buns conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for bread, rolls or buns by § 136.110 except that:

(1) The only moistening ingredient permitted in the preparation of the dough is milk or, as an alternative, a combination of dairy products in such a proportion that the weight of the nonfat milk solids is not more than 2.3 times and not less than 1.2 times the weight of the milkfat therein, with or without water, in a quantity that provides not less than 8.2 parts milk solids for each 100 parts by weight of flour.

(2) No buttermilk, buttermilk product, cheese whey, cheese whey product, or milk protein is used.

(b) The name of the food is "milk bread", "milk rolls", "milk buns", as applicable.

§ 136.160 Raisin bread, rolls, and buns.

(a) Each of the foods raisin bread, raisin rolls, and raisin buns conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for bread, rolls or buns by § 136.110, except that:

(1) Not less than 50 parts by weight of seeded or seedless raisins are used for each 100 parts by weight of flour used.

(2) Water extract of raisins may be used, but not to replace raisins.

(3) The baked units may bear icing or frosting.

(4) The limitation prescribed by § 136.110(c)(6) on the quantity and composition of milk and/or other dairy products does not apply.

(5) The total solids are determined by the method prescribed in § 136.110(d), except that sec. 14.083(b) on page 235 of "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. 1975,[1] will apply.

(b) The name of the food is "raisin bread", "raisin rolls", "raisin buns", as applicable. When the food contains not less than 2.56 percent by weight of whole egg solids, the name of the food may be "raisin and egg bread", "raisin and egg rolls", or "raisin and egg buns", as applicable, accompanied by the statement "Contains ____ medium-sized egg(s) per pound" in the manner prescribed by § 102.5(c)(3) of this chapter, the blank to be filled in with the number which represents the whole egg content of the food expressed to the nearest one-fifth egg but not greater than the amount actually present. For purposes of this regulation, whole egg solids are the edible contents of eggs calculated on a moisture-free basis and exclusive of any nonegg solids which may be present in standardized and other commercial egg products. One medium-sized egg is equivalent to 0.41 ounce of whole egg solids.

NOTE.—The confirmation of effective date for §136.160 (formerly § 17.40) published in the FEDERAL REGISTER of October 15, 1976 (41 FR 45540) stated that the provisions of § 136.160(b), as they pertain to the use of the word "egg" in the name of the food, are stayed pending full review of the objections and requests for hearing.

§ 136.165 Enriched raisin bread, rolls, and buns.

(a) Each of the foods enriched raisin bread, enriched raisin rolls, and enriched raisin buns conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for raisin bread, raisin rolls, and raisin buns by § 136.160, except that the specifications in § 136.115 (a)(1) through (7) shall apply.

(b) The name of the food is "enriched raisin bread", "enriched raisin rolls", or "enriched raisin buns", as applicable. When the food contains not less than 2.56 percent by weight of whole egg solids, the name of the food may be "enriched raisin and egg bread", "enriched raisin and egg rolls", or "enriched raisin and egg buns", as applicable, accompanied by the statement "Contains _____ medium-sized egg(s) per pound" in the manner prescribed by § 102.5(c)(3) of this chapter, the blank to be filled in with the number which represents the whole egg content of the food expressed to the nearest one-fifth egg but not greater than the amount actually present. For purposes of this regulation, whole egg solids are the edible contents of eggs calculated on a moisture-free basis and exclusive of any nonegg solids which may be present in standardized and other commercial egg products. One medium-sized egg is equivalent to 0.41 ounce of whole egg solids. The term "milk" may be included in the name of the food if the food complies with the requirements for milk and/or other dairy products in § 136.130.

NOTE. Since the provisions of § 136.165 (formerly § 17.60) relating to the use of the word "egg" in the name of the food are predicated on stayed provisions of §§ 136.110, 136.115 and 136.160, none of paragraph (b) of § 136.165 except the first and last sentences, will be effective while the issues remain unresolved.

§ 136.180 Whole wheat bread, rolls, and buns.

(a) Each of the foods whole wheat bread, graham bread, entire wheat bread, whole wheat rolls, graham rolls, entire wheat rolls, whole wheat buns, graham buns, and entire wheat buns conforms to the definition and standard of identity and is subject to the label statement of ingredients prescribed for bread, rolls and buns by § 136.110, except that:

(1) The dough is made from the optional ingredient whole wheat flour, bromated whole wheat flour, or a combination of these. No flour, bromated flour, or phosphated flour is used. The potassium bromate in any bromated whole wheat flour used is deemed to be an additional optional ingredient in the whole wheat bread, whole wheat rolls, or whole wheat buns.

(2) The limitation prescribed by § 136.110(c)(6) on the quantity and composition of milk and/or other dairy products does not apply.

(b) The name of the food is "whole wheat bread", "graham bread", "entire wheat bread", "whole wheat rolls", "graham rolls", "entire wheat rolls", "whole wheat buns", "graham buns", "entire wheat buns", as applicable.

PART 137—CEREAL FLOURS AND RELATED PRODUCTS

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Cereal Flours and Related Products

Sec.

137.105 Flour.
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137.285 Degerminated yellow corn meal.
137.290 Self-rising yellow corn meal.
137.300 Farina.
137.305 Enriched farina.
137.320 Semolina.
137.350 Enriched rice.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046 as amended, 1055–1056 as amended (21 U.S.C. 341, 371).

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Cereal Flours and Related Products

§ 137.105 Flour.

(a) Flour, white flour, wheat flour, plain flour, is the food prepared by grinding and bolting cleaned wheat,

other than durum wheat and red durum wheat. To compensate for any natural deficiency of enzymes, malted wheat, malted wheat flour, malted barley flour, or any combination of two or more of these, may be used; but the quantity of malted barley flour so used is not more than 0.75 percent. Harmless preparations of α-amylase obtained from *Aspergillus oryzae*, alone or in a safe and suitable carrier, may be used. When tested for granulation as prescribed in paragraph (c)(4) of this section, not less than 98 percent of the flour passes through a cloth having openings not larger than those of woven wire cloth designated "212 μm (No. 70)" in Table I of "Annual Book of ASTM Standards, Part 30" published in 1972 by the American Society for Testing and Materials.* The flour is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than the sum of 1/20 of the percent of protein therein, calculated to a moisture-free basis, plus 0.35. Its moisture content is not more than 15 percent. It may contain ascorbic acid in a quantity not to exceed 200 parts per million as a dough conditioner. Unless such addition conceals damage or inferiority or makes the flour appear to be better or of greater value than it is, one or any combination of two or more of the following optional bleaching ingredients may be added in a quantity not more than sufficient for bleaching or, in case such ingredient has an artificial aging effect; in a quantity not more than sufficient for bleaching and such artificial aging effect:

(1) Oxides of nitrogen.
(2) Chlorine.
(3) Nitrosyl chloride.
(4) Chlorine dioxide.
(5) One part by weight of benzoyl peroxide mixed with not more than six parts by weight of one or any mixture of two or more of the following: potassium alum, calcium sulfate, magnesium carbonate, sodium aluminum sulfate, dicalcium phosphate, tricalcium phosphate, starch, calcium carbonate.
(6) Acetone peroxides complying with the provisions of § 172.802 of this chapter.
(7) Azodicarbonamide (complying with the requirements of § 172.806 of this chapter, including the quantitative limit of not more than 45 parts per million).

(b)(1) All optional ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(2) When ascorbic acid is added, the label shall bear the statement "Ascorbic acid added as a dough conditioner". When the optional ingredient "α-amylase obtained from *Aspergillus oryzae*" is used, it shall be declared in the list of ingredients by that name. When any optional bleaching ingredient is used, the label shall bear the word "Bleached". Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the word "Bleached" shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of a trademark or brand, other written, printed or graphic matter, which is also a part of such trademark or brand, may so intervene if the word "Bleached" is in such juxtaposition with such trademark or brand as to be conspicuously related to such name.

(c) For the purposes of this section:

(1) Ash is determined by the method prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Edition, 1940, page 212, under "Method I—Official." [Ed. note, 10th edition, 1965, p. 191, sec. 13.006.] Ash is calculated to a moisture-free basis by subtracting the percent of moisture in the flour from 100, dividing the remainder into the percent of ash, and multiplying the quotient by 100.

(2) Protein is 5.7 times the nitrogen as determined by the method prescribed in such book on page 26, under "Kjeldahl-Gunning-Arnold Method—Official." [Ed. note, 10th edition, 1965, p. 16, "Improved Kjeldahl Methods for Nitrate-Free Samples—Official," sec. 2.044.] Protein is calculated to a moisture-free basis by subtracting the percent of moisture in the flour from 100, dividing the remainder into the percent of protein, and multiplying the quotient by 100.

(3) Moisture is determined by the method prescribed in such book on page 211, under "Vacuum Oven Method—Official." [Ed. note, 10th edition, 1965, p. 191, secs. 13.002, 13.003.]

(4) Granulation is determined as follows: Use No. 70 sieve complying with specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L.C. 584 of the United States Department of Commerce, National Bureau of Standards. Attach bottom pan to sieve in Ro-Tap sifter (or an equivalent sifter). Place half of a rubber ball or other sieving aid in the sieve. Pour 100 grams of the sample in the sieve and turn on the sifter with knocker. Sift exactly 5 minutes. Weigh the residue on the No. 70 sieve and convert to percentage.

§ 137.155 Bromated flour.

Bromated flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for flour by § 137.105, except that potassium bromate is added in a quantity not exceeding 50 parts to each million parts of the finished bromated flour, and is added only to flours whose baking qualities are improved by such addition.

§ 137.160 Enriched bromated flour.

Enriched bromated flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed or enriched flour by § 137.165, except that potassium bromate is added in a quantity not exceeding 50 parts to each million parts of the finished enriched bromated flour, and is added only to enriched flours whose baking qualities are improved by such addition.

§ 137.165 Enriched flour.

Enriched flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for flour by § 137.105 except that:

(a) It contains in each pound 2.9 milligrams of thiamine, 1.8 milligrams of riboflavin, 24 milligrams of niacin, and 40 milligrams of iron;

(b) It may contain added calcium in such quantity that the total calcium content is 960 milligrams per pound. Enriched flour may be acidified with monocalcium phosphate within the limits prescribed by § 137.175 for phosphated flour, but, if insufficient additional calcium is present to meet the 960 milligram level, no claim may be made on the label for calcium as a nutrient;

(c) The requirement of paragraphs (a) and (b) of this section will be deemed to have been met if reasonable overages of the vitamins and minerals, within the limits of good manufacturing practice, are present to insure that the required levels of the vitamins and minerals are maintained throughout the expected shelf life of the food under customary conditions of distribution and storage. The quantitative content of the following vitamins shall be calculated in terms of the following chemically identifiable reference forms:

Vitamin	Reference form		
	Name	Empirical formula	Molecular weight
Thiamine	Thiamine chloride hydrochloride.	$C_{12}H_{17}ClN_4OS \cdot HCl$	337.28
Riboflavin	Riboflavin	$C_{17}H_{20}N_4O_6$	376.37
Niacin	Niacin	$C_6H_5NO_2$	123.11

(d) It may contain not more than 5 percent by weight of wheat germ or partly defatted wheat germ;

(e) In determining whether the ash content complies with the requirements of this section, ash resulting from any added iron or salts of iron or calcium or wheat germ is excluded in calculating ash content.

(f) All ingredients from which the food is fabricated shall be safe and suitable. The vitamins and minerals added to the food for enrichment purposes may be supplied by any safe and suitable substance. Niacin equivalents as derived from tryptophan content shall not be used in determining total niacin content.

EFFECTIVE DATE NOTE: The iron content in revised § 137.165(a) (formerly § 15.10(a)) of "40 milligrams" was stayed at 39 FR 5189, pending the outcome of a hearing. The levels of iron shall remain at the level "not less than 13.0 milligrams and not more than 16.5 milligrams" prescribed by the former § 15.10(a) prior to amendment of the section.

*Copies may be obtained from: American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.

§ 137.170 Instantized flours.

(a) Instantized flours, instant blending flours, quick-mixing flours, are the foods each of which conforms to the definition and standard of identity and is subject to the requirement for label statement of optional ingredients prescribed for the corresponding kind of flour by §§ 137.105, 137.155, 137.160, 137.165, 137.175, 137.180, and 137.185, except that each such flour has been made by one of the optional procedures set forth in paragraph (b) of this section, and is thereby made readily pourable. Such flour will all pass through a No. 20 mesh U.S. standard sieve (840-micron opening), and not more than 20 percent will pass through a 200 mesh U.S. standard sieve (74-micron opening).

(b) The optional procedures referred to in paragraph (a) of this section are:

(1) A selective grinding and bolting procedure or other milling procedure, whereby controlled techniques are used to obtain a food too fine to meet the granulation specification prescribed in § 137.300(a) for farina.

(2) An agglomerating procedure, whereby flour that originally meets the granulation specification prescribed in § 137.105(a) has been modified by further processing, so that a number of the individual flour particles have been combined into agglomerates conforming to the granulation specifications set out in paragraph (a) of this section.

(c) The name of each product covered by this section is the name prescribed by the definition and standard of identity for the corresponding kind of flour as referred to in paragraph (a) of this section, preceded immediately and conspicuously by the words "Instantized", "Instant blending", or "Quick-mixing".

§ 137.175 Phosphated flour.

Phosphated flour, phosphated white flour, phosphated wheat flour, conforms to the definition and standard of identity, and is subject to the requirements for label declaration of optional ingredients, prescribed for flour by § 137.105, except that:

(a) Monocalcium phosphate is added in a quantity not less than 0.25 percent and not more than 0.75 percent of the weight of the finished phosphated flour; and

(b) In determining whether the ash content complies with the requirements of this section allowance is made for the added monocalcium phosphate.

§ 137.180 Self-rising flour.

(a) Self-rising flour, self-rising white flour, self-rising wheat flour, is an intimate mixture of flour, sodium bicarbonate, and one or more of the acid-reacting substances monocalcium phosphate, sodium acid pyrophosphate, and sodium aluminum phosphate. It is seasoned with salt. When it is tested by the method prescribed in paragraph (c) of this section not less than 0.5 percent of carbon dioxide is evolved. The acid-reacting substance is added in sufficient quantity to neutralize the sodium bicarbonate. The combined weight of such acid-reacting substance and sodium bicarbonate is not more than 4.5 parts to each 100 parts of flour used. Subject to the conditions and restrictions prescribed by § 137.105(a), the bleaching ingredients specified in such section may be added as optional ingredients. If the flour used in making the self-rising flour is bleached, the optional bleaching ingredient used therein (see § 137.105(a)) is also an optional ingredient of the self-rising flour.

(b) All optional ingredients in self-rising flour, including any contributed by the flour used, shall be declared on the label as required by the applicable sections of Part 101 of this chapter and § 137.105(b)(2), as appropriate.

(c) The method referred to in paragraph (a) of this section is the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th edition, 1940, beginning on page 186 [Ed. note, 10th edition, 1965, p. 119, secs. 7.002, 7.003], under "Gasometric Method with Chittick's Apparatus—Official," except that the following procedure is substituted for the procedure specified therein under "6—Determination":

(1) Weigh 17 grams of the official sample into flask A, add 15–20 glass beads (4–6 mm. diameter), and connect this flask with the apparatus (fig. 22). Open stopcock C and by means of the leveling bulb E bring the displacement solution to the 25 cc. graduation above the zero mark. (This 25 cc. is a partial allowance for the volume of acid to be used in the decomposition.) Allow the apparatus to stand 1–2 minutes to insure that the temperature and pressure within the apparatus are the same as those of the room. Close the stopcock, lower the leveling bulb somewhat to reduce the pressure within the apparatus, and slowly run into the decomposition flask from burette F 45 cc. of sulfuric acid (1+5). To prevent the liberated carbon dioxide from escaping through the acid burette into the air, keep the displacement solution in the leveling bulb at all times during the decomposition at a lower level than that in the gas-measuring tube. Rotate and then vigorously agitate the decomposition flask for three minutes to mix the contents intimately. Allow to stand for 10 minutes to bring to equilibrium. Equalize the pressure in the measuring tube by means of the leveling bulb and read the volume of gas from the zero point on the tube. Deduct 20 cc. from this reading (this 20 cc. together with previous allowance of 25 cc. compensates for the 45 cc. acid used in the decomposition). Observe the temperature of the air surrounding the apparatus and also the barometric pressure and multiply the number of cc. of gas evolved by the factor given in Table 24—Chapter XLIII [Ed. note, 10th edition, 1965, p. 887, sec. 43.028] for the temperature and pressure observed. Divide the corrected reading by 100 to obtain the apparent percent by weight of carbon dioxide in the official sample.

(2) Correct the apparent percent of carbon dioxide to compensate for varying atmospheric conditions by immediately assaying a synthetic sample by the same method in the same apparatus.

(3) Prepare the synthetic sample with 16.2 grams of flour, 0.30 gram of monocalcium phosphate, 0.30 gram of salt, and a sufficient quantity of sodium bicarbonate U.S.P. (dried over sulfuric acid) to yield the amount of carbon dioxide recovered in assay of official sample. Determine this quantity by multiplying weight of carbon dioxide recovered in assay of official sample by 1.91.

(4) Divide the weight of carbon dioxide recovered from synthetic sample by weight of carbon dioxide contained in sodium bicarbonate used.

(5) Divide the quotient into the apparent percent of carbon dioxide in official sample to obtain percent of carbon dioxide evolved from the official sample.

§ 137.185 Enriched self-rising flour.

Enriched self-rising flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for self-rising flour by § 137.180, except that:

(a) It contains in each pound 2.9 milligrams of thiamine, 1.8 milligrams of riboflavin, 24 milligrams of niacin, and 40 milligrams of iron;

(b) It contains added calcium in such quantity that the total calcium content is 960 milligrams per pound. If a calcium compound is added for technical purposes to give self-rising characteristics to the flour, the amount of calcium per pound of flour may exceed 960 milligrams provided that the excess is no greater than necessary to accomplish the intended effect. However, if such calcium is insufficient to meet the 960-milligram level, no claim may be made on the label for calcium as a nutrient.

(c) The requirements of paragraphs (a) and (b) of this section will be deemed to have been met if reasonable overages of the vitamins and minerals, within the limits of good manufacturing practice, are present to insure that the required levels of the vitamins and minerals are maintained throughout the expected shelf life of the food under customary conditions of distribution and storage. The quantitative content of the following vitamins shall be calculated in terms of the following chemically identifiable reference forms:

Vitamin	Reference form		
	Name	Empirical formula	Molecular weight
Thiamine	Thiamine chloride hydrochloride.	$C_{12}H_{17}ClN_4OS \cdot HCl$	337.2
Riboflavin	Riboflavin	$C_{17}H_{20}N_4O_6$	376.37
Niacin	Niacin	$C_6H_5NO_2$	123.11

(d) It may contain not more than 5 percent by weight of wheat germ or partly defatted wheat germ;

(e) When calcium is added as dicalcium phosphate, such dicalcium phosphate is also considered to be an acid-reacting substance;

(f) When calcium is added as carbonate, the method set forth in § 137.180

(c) does not apply as a test for carbon dioxide evolved; but in such case the quantity of carbon dioxide evolved under ordinary conditions of use of the enriched self-rising flour is not less than 0.5 percent of the weight thereof;

(g) All ingredients from which the food is fabricated shall be safe and suitable. The vitamins and minerals added to the food for enrichment purposes may be supplied by any safe and suitable substances. Niacin equivalents as derived from tryptophan content shall not be used in determining total niacin content.

EFFECTIVE DATE NOTE: The iron content in revised § 137.165(a) (formerly § 15.60(a)) of "40 milligrams" was stayed at 39 FR 5189, pending the outcome of a hearing. The levels of iron shall remain at the level "not less than 13.0 milligrams and not more than 16.5 milligrams" prescribed by the former § 15.60(a) prior to amendment of the section.

§ 137.190 Cracked wheat.

Cracked wheat is the food prepared by so cracking or cutting into angular fragments cleaned wheat other than durum wheat and red durum wheat that, when tested by the method prescribed in § 137.200(c)(2), not less than 90 percent passes through a No. 8 sieve and not more than 20 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. Cracked wheat contains not more than 15 percent of moisture as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page 353 [Ed. note, 10th edition, 1965, p. 327, secs. 22.002, 22.003], under "Preparation of Sample—Official" and "Moisture I. Drying with Heat—Official."

§ 137.195 Crushed wheat.

Crushed wheat, coarse ground wheat, is the food prepared by so crushing cleaned wheat other than durum wheat and red durum wheat that, when tested by the method prescribed in § 137.200(c)(2), 40 percent or more passes through a No. 8 sieve and less than 50 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. Crushed wheat contains not more than 15 percent of moisture as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th edition, 1940, page 353 [Ed. note, 10th edition, 1965, p. 327, secs. 22.002, 22.003], under "Preparation of Sample—Official" and "Moisture I. Drying with Heat—Official."

§ 137.200 Whole wheat flour.

(a) Whole wheat flour, graham flour, entire wheat flour is the food prepared by so grinding cleaned wheat, other than durum wheat and red durum wheat, that when tested by the method prescribed in paragraph (c)(2) of this section, not less than 90 percent passes through a 2.36 mm (No. 8) sieve and not less than 50 percent passes through a 850 μm (No. 20) sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. To compensate for any natural deficiency of enzymes, malted wheat, malted wheat flour, malted barley flour, or any combination of two or more of these, may be used; but the quantity of malted barley flour so used is not more than 0.75 percent. It may contain harmless preparations of α-amylase obtained from *Aspergillus oryzae*, alone or in a safe and suitable carrier. The moisture content of whole wheat flour is not more than 15 percent. It may contain ascorbic acid in a quantity not to exceed 200 parts per million as a dough conditioner. Unless such addition conceals damage or inferiority or makes the whole wheat flour appear to be better or of greater value than it is, the optional bleaching ingredient azodicarbonamide (complying with the requirements of § 172.806 of this chapter, including the quantative limit of not more than 45 parts per million) or chlorine dioxide, or chlorine, or a mixture of nitrosyl chloride and chlorine, may be added in a quantity not more than sufficient for bleaching and artificial aging effects.

(b)(1) All optional ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(2) When ascorbic acid is added, the label shall bear the statement "Ascorbic acid added as a dough conditioner". When the optional ingredient "α-amylase obtained from *Aspergillus oryzae*" is used, it shall be declared by that name in the list of ingredients. When any optional bleaching ingredient is used, the label shall bear the word "Bleached". Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the word "Bleached" shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of a trademark or brand, other written, printed, or graphic matter, which is also a part of such trademark or brand, may so intervene if the word "Bleached" is in such juxtaposition with such trademark or brand as to be conspicuously related to such name.

(c) For the purposes of this section:

(1) Moisture is determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Edition, 1940, page 211, under "Vacuum Oven Method—Official." [Ed. note, 10th edition, 1965, p. 191, secs. 13.002, 13.005.]

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 8 and No. 20 sieves, having standard 8-inch full height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the U.S. Department of Commerce, National Bureau of Standards. Fit a No. 8 sieve into a No. 20 sieve. Attach bottom pan to the No. 20 sieve. Pour 100 gm. of the sample into the No. 8 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution each time in the same direction, after each 25 strokes. Continue shaking for 2 minutes. Weigh the material which fails to pass through the No. 8 sieve and the material which passes through the No. 20 sieve.

§ 137.205 Bromated whole wheat flour.

Bromated whole wheat flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for whole wheat flour by § 137.200, except that potassium bromate is added in a quantity not exceeding 75 parts to each million parts of finished bromated whole wheat flour.

§ 137.211 White corn flour.

(a) White corn flour is the food prepared by so grinding and bolting cleaned white corn that when tested by the method prescribed in paragraph (b)(2) of this section, not less than 98 percent passes through a No. 50 sieve and not less than a 50 percent passes through No. 70 woven-wire cloth. Its moisture content is not more than 15 percent. In its preparation, part of the ground corn may be removed, but in any such case, the content (on a moisture-free basis) of neither the crude fiber nor fat in the finished white corn flour exceeds the content (on a moisture-free basis) of such substance in the cleaned corn from which it was ground.

(b)(1) For the purpose of this section, moisture, fat, and crude fiber are determined by methods therefor referred to in § 137.250 (b)(1).

(2) The method referred to in paragraph (a) of this section is as follows: Weigh 5 grams of sample into a tared truncated metal cone (top diameter 5 centimeters, bottom diameter 2 centimeters, height 4 centimeters), fitted at bottom with 70-mesh wire cloth complying with the specifications for No. 70 wire cloth in "Standard Specifications for Sieves," published March 1, 1940 in L. C. 584 of the Bureau of Standards, United States Department of Commerce. Attach cone to a suction flask. Wash with 150 ml. of petroleum ether applied in a small stream without suction, while gently stirring the sample with a small glass rod. Apply suction for 2 minutes after washing is completed, then shake the cone for 2 minutes with a vigorous horizontal motion, striking the side against the hand, and then weigh. The decrease in weight of sample, calculated as percent by weight of sample shall be considered the percent passing through No. 70 wire cloth. Transfer the residue from cone to a No. 50 sieve having a standard 8-inch diameter full-height frame, complying with the specifications for wire cloth and sieve frame in said "Standard Specifications for Sieves." Shake for 2 minutes with a vigorous horizontal motion, striking the side against the hand; remove and weigh the residue; calculate the weight of residue

as percent by weight of sample, and subtract from 100 percent to obtain the percent of sample passing through the No. 50 sieve.

§ 137.215 Yellow corn flour.

Yellow corn flour conforms to the definition and standard of identity prescribed by § 137.211 for white corn flour except that cleaned yellow corn is used instead of clean white corn.

§ 137.220 Durum flour.

(a) Durum flour is the food prepared by grinding and bolting cleaned durum wheat. When tested for granulation as prescribed in § 137.105(c)(4), not less than 98 percent of such flour passes through the No. 70 sieve. It is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 1.5 percent. Its moisture content is not more than 15 percent.

(b) For the purpose of this section, ash, moisture, and granulation are determined by the methods prescribed in § 137.105(c).

§ 137.225 Whole durum flour.

Whole durum wheat flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for whole wheat flour by § 137.200, except that cleaned durum wheat, instead of cleaned wheat other than durum wheat and red durum wheat, is used in its preparation.

§ 137.230 Corn grits.

(a) Grits, corn grits, hominy grits, is the food prepared by so grinding and sifting cleaned white corn, with removal of corn bran and germ, that:

(1) On a moisture-free basis its crude fiber content is not more than 1.2 percent and its fat content is not more than 2.25 percent; and

(2) When tested by the method prescribed in paragraph (b)(2) of this section not less than 95 percent passes through a No. 10 sieve but not more than 20 percent through a No. 25 sieve.

(b)(1) For the purposes of this section moisture, fat, and crude fiber are determined by methods therefor referred to in § 137.250(b)(1).

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 10 and No. 25 sieves, having standard 8-inch diameter full-height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the Bureau of Standards, United States Department of Commerce. Attach bottom pan to No. 25 sieve. Fit the No. 10 sieve into the No. 25 sieve. Pour 100 grams of sample into the No. 10 sieve, attach cover and hold assembly in a slightly inclined position, shake the sieves by striking the sides against one hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution each time in the same direction after each 25 strokes. Continue shaking for 2 minutes. Weigh separately the material remaining on the No. 10 sieve and in the pan, and calculate each weight as percent of sample. The percent of sample passing through a No. 10 sieve shall be determined by subtracting from 100 percent the percent remaining on the No. 10 sieve. The percent of material in the pan shall be considered as the percent passing through a No. 25 sieve.

§ 137.235 Enriched corn grits.

(a) Enriched corn grits are the foods, each of which conforms to the definition and standard of identity prescribed for grits, yellow grits, or quick cooking grits by §§ 137.230, 137.240, and 137.245, except that:

(1) It contains in each pound not less than 2.0 mg. and not more than 3.0 mg. of thiamine, not less than 1.2 mg. and not more than 1.8 mg. of riboflavin, not less than 16 mg. and not more than 24 mg. of niacin or niacinamide, not less than 13 mg. and not more than 26 mg. of iron (Fe);

(2) It may contain in each pound not less than 250 U.S.P. units and not more than 1,000 U.S.P. units of vitamin D; and

(3) It may contain in each pound not less than 500 mg. and not more than 750 mg. of calcium (Ca). Iron and calcium may be added only in forms which are harmless and assimilable. The vitamins referred to in paragraph (a)(1) of this section may be combined with harmless substances to render them insoluble in water if the water-insoluble products are assimilable. The substances referred to in this subparagraph and in paragraphs (a)(1) and (2) of this section may be added in a harmless carrier; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the kind of corn grits used. Dried yeast in quantities not exceeding 1.5 percent by weight of the finished food may be used.

(b) The name of each kind of enriched corn grits is the word "Enriched" followed by the name of the kind of corn grits used which is prescribed in the definition and standard of identity therefor.

§ 137.240 Quick grits.

(a) Quick grits, quick cooking grits are the foods, each of which conforms to the definition and standard of identity prescribed for a kind of grits by §§ 137.230 or 137.245, except that in process of preparation the grits are lightly steamed and slightly compressed so as to fracture the particles.

(b) The name of each kind of grits is "Quick" or "Quick cooking" followed by the name of the kind of grits used which is prescribed in the definition and standard of identity therefor.

§ 137.245 Yellow grits.

Yellow grits, yellow corn grits, yellow hominy grits, conforms to the definition and standard of identity prescribed by § 137.230 for grits except that cleaned yellow corn is used instead of cleaned white corn.

§ 137.250 White corn meal.

(a) White corn meal is the food prepared by so grinding cleaned white corn that when tested by the method prescribed in paragraph (b)(2) of this section not less than 95 percent passes through a No. 12 sieve, not less than 45 percent through a No. 25 sieve, but not more than 35 percent through a No. 72 grits gauze. Its moisture content is not more than 15 percent. In its preparation coarse particles of the ground corn may be separated and discarded, or reground and recombined with all or part of the material from which they were separated, but in any such case the crude fiber content of the finished corn meal is not less than 1.2 percent and not more than that of the cleaned corn from which it was ground, and its fat content does not differ more than 0.3 percent from that of such corn. The contents of crude fiber and fat in all the foregoing provisions relating thereto are on a moisture-free basis.

(b)(1) For the purposes of this section moisture is determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 6th edition, page 259, sections 20.70 and 20.71 [Ed. note, 10th edition, 1965, p. 202, secs. 13.058, 13.059], fat is determined by the method prescribed on pages 259 and 260, sections 20.70 and 20.73 [Ed. note, 10th edition, 1965, p. 202, secs. 13.058, 13.063]; and crude fiber determined by the method prescribed on pages 259 and 260, sections 20.70 and 20.74 [Ed. note, 10th edition, 1965, p. 202, secs. 13.058, 13.061].

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 12 and No. 25 sieves, having standard 8-inch diameter, full-height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L.C. 584 of the Bureau of Standards, United States Department of Commerce. A sieve with frame of the same dimensions as the Nos. 12 and 25 and fitted with 72 XXX grits gauze is used as the third sieve. It is referred to hereafter as the No. 72 sieve. The 72 XXX grits gauze has openings equivalent in size with those of No. 70 woven-wire cloth, complying with specifications for such cloth contained in such "Standard Specifications for Sieves." Attach bottom pan to No. 72 sieve. Fit the No. 25 sieve into the No. 72 sieve and the No. 12 sieve into the No. 25 sieve. Pour 100 grams of sample into the No. 12 sieve, attach cover and hold the assembly in a slightly inclined position and shake the assembly of sieves by striking the sides against one hand with an upward stroke, at the rate of about 150 times per minute. Turn the assembly of sieves about one-sixth of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for 2 minutes. Weigh separately the material remaining on each sieve and in the pan, and calculate each weight as percent of sample. Sometimes when meals are tested, fine particles clog the sieve open-

ings. If any sieve is clogged by fine material smaller than its openings, empty the contents onto a piece of paper. Remove the entrapped material on the bottom of the sieve by a hair brush and add to the sieve below. In like manner, clean the adhering material from inside the sieve and add to the material on the paper. Return mixture on the paper to the sieve, reassemble the sieves, and shake in the same manner as before for 1 minute. Repeat cleaning procedure if necessary until a 5-gram or less loss in weight occurs in any sieve during a 1-minute shaking. The percent of sample passing through No. 12 sieve shall be determined by subtracting from 100 percent, the percent of material remaining on the No. 12 sieve. The percent passing through a No. 25 sieve shall be determined by adding the percents remaining on the No. 72 sieve and the percent in pan. The percent in the pan shall be considered as the percent passing through a No. 72 XXX grits gauze.

§ 137.255 Bolted white corn meal.

(a) Bolted white corn meal is the food prepared by so grinding and sifting cleaned white corn that:

(1) Its crude fiber content is less than 1.2 percent but its fat content is not less than 2.25 percent; and

(2) When tested by the method prescribed in § 137.250(b)(2), except that a No. 20 standard sieve is used instead of the No. 12 sieve, not less than 95 percent passes through a No. 20 sieve, not less than 45 percent through a No. 25 sieve, but not more than 25 percent through No. 72 XXX grits gauze. Its moisture content is not more than 15 percent. In its preparation particles of ground corn which contain germ may be separated, reground, and recombined with all or part of the material from which it was separated, but in any such case the fat content of the finished bolted white corn meal does not exceed by more than 0.3 percent the fat content of the cleaned corn from which it was ground. The contents of crude fiber and fat in all the foregoing provisions relating thereto are on a moisture-free basis.

(b) For the purposes of this section, moisture, fat and crude fiber are determined by the methods therefor referred to in § 137.250(b)(1).

§ 137.260 Enriched corn meals.

(a) Enriched corn meals are the foods, each of which conforms to the definition and standard of identity prescribed for a kind of corn meal by §§ 137.250, 137.255, 137.265, 137.270, 137.275, 137.280, 137.285, and 137.290, except that:

(1) It contains in each pound not less than 2.0 mg. and not more than 3.0 mg. of thiamine, not less than 1.2 mg. and not more than 1.8 mg. of riboflavin, not less than 16 mg. and not more than 24 mg. of niacin or niacinamide, and not less than 13 mg. and not more than 26 mg. of iron (Fe);

(2) It may contain in each pound not less than 250 U. S. P. units and not more than 1,000 U. S. P. units of vitamin D; and

(3) It may contain in each pound not less than 500 milligrams and not more than 750 milligrams of calcium (Ca); *Provided, however,* That enriched self-rising corn meals shall contain in each pound not more than 1,750 milligrams of calcium (Ca). Iron and calcium may be added only in forms which are harmless and assimilable. The substances referred to in this paragraph (a)(3) and in paragraphs (a)(1) and (2) of this section may be added in a harmless carrier which does not impair the enriched corn meal; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the kind of corn meal used. Dried yeast in quantities not exceeding 1.5 percent by weight of the finished food may be used.

(b) The name of each kind of enriched corn meal is the word "Enriched" followed by the name of the kind of corn meal used which is prescribed in the definition and standard of identity therefor.

§ 137.265 Degerminated white corn meal.

(a) Degerminated white corn meal, degermed white corn meal, is the food prepared by grinding cleaned white corn and removing bran and germ so that:

(1) On a moisture-free basis, its crude fiber content is less than 1.2 percent and its fat content is less than 2.25 percent; and

(2) When tested by the method prescribed in § 137.250(b)(2), except that a No. 20 standard sieve is used instead of a No. 12 sieve, not less than 95 percent passes through a No. 20 sieve, not less than 45 percent through a No. 25 sieve, but not more than 25 percent through No. 72 XXX grits gauze. Its moisture content is not more than 15 percent.

(b) For the purposes of this section, moisture, fat and crude fiber are determined by methods therefor referred to in § 137.250(b)(1).

§ 137.270 Self-rising white corn meal.

(a) Self-rising white corn meal is an intimate mixture of white corn meal, sodium bicarbonate, and one or both of the acid-reacting substances monocalcium phosphate and sodium aluminum phosphate. It is seasoned with salt. When it is tested by the method prescribed in paragraph (b) of this section, not less than 0.5 percent of carbon dioxide is evolved. The acid-reacting substance is added in sufficient quantity to neutralize the sodium bicarbonate. The combined weight of such acid-reacting substance and sodium bicarbonate is not more than 4.5 parts to each 100 parts of white corn meal used.

(b) The method referred to in paragraph (a) of this section is the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 6th Edition, beginning on page 208 [Ed. note, 10th edition, 1965, p. 119, secs. 7.002, 7.003] under "Gasometric Method (2) with Chittick's Apparatus—Official," except that the following procedure is substituted for the procedure specified therein under "17.6—Determination":

(1) Weigh 17 grams of the official sample into flask *A*, add 15–20 glass beads (4–6 mm. diameter), and connect this flask with the apparatus (fig. 25). Open stopcock *C* and by means of the leveling bulk *F* bring the displacement solution to the 25 cc. graduation above the zero mark. (This 25 cc. is a partial allowance for the volume of acid to be used in the decomposition.) Allow the apparatus to stand 1–2 minutes to insure that the temperature and pressure within the apparatus are the same as those of the room. Close the stopcock, lower the leveling bulb somewhat to reduce the pressure within the apparatus, and slowly run into the decomposition flask from burette *F* 45 cc. of sulfuric acid (1+5). To prevent the liberated carbon dioxide from escaping through the acid burette into the air, keep the displacement solution in the leveling bulb at all times during the decomposition at a lower level than that in the gas-measuring tube. Rotate and then vigorously agitate the decomposition flask for 3 minutes to mix the contents intimately. Allow to stand for 10 minutes to bring to equilibrium. Equalize the pressure in the measuring tube by means of the leveling bulb and read the volume of gas from the zero point on the tube. Deduct 20 cc. from this reading (this 20 cc. together with previous allowance of 25 cc. compensates for the 45 cc. acid used in the decomposition). Observe the temperature of the air surrounding the apparatus and also the barometric pressure and multiply the number of cc. of gas evolved by the factor given in Table 44.30 [Ed. note, 10th edition, 1965, p. 887, sec. 43.028]—Reference Tables for the temperature and pressure observed. Divide the corrected reading by 100 to obtain the apparent percent by weight of carbon dioxide in the official sample.

(2) Correct the apparent percent of carbon dioxide to compensate for varying atmospheric conditions by immediately assaying a synthetic sample by the same method in the same apparatus.

(3) Prepare the synthetic sample with 16.2 grams of corn meal, 0.30 gram of monocalcium phosphate, 0.30 gram of salt, and a sufficient quantity of sodium bicarbonate U.S.P. (dried over sulfuric acid) to yield the amount of carbon dioxide recovered in assay of official sample. Determine this quantity by multiplying weight of carbon dioxide recovered in assay of official sample by 1.91.

(4) Divide the weight of carbon dioxide recovered from synthetic sample by weight of carbon dioxide contained in sodium bicarbonate used.

(5) Divide the quotient into the apparent percent of carbon dioxide in official sample to obtain percent of carbon dioxide evolved from the official sample.

§ 137.275 Yellow corn meal.

Yellow corn meal conforms to the definition and standard of identity pre-

scribed by § 137.250 for white corn meal except that cleaned yellow corn is used instead of cleaned white corn.

§ 137.280 Bolted yellow corn meal.

Bolted yellow corn meal conforms to the definition and standard of identity prescribed by § 137.255 for bolted white corn meal except that cleaned yellow corn is used instead of cleaned white corn.

§ 137.285 Degerminated yellow corn meal.

Degerminated yellow corn meal, degermed yellow corn meal, conforms to the definition and standard of identity prescribed by § 137.265 for degerminated white corn meal except that cleaned yellow corn is used instead of cleaned white corn.

§ 137.290 Self-rising yellow corn meal.

Self-rising yellow corn meal conforms to the definition and standard of identity prescribed by § 137.270 for self-rising white corn meal except that yellow corn meal is used instead of white corn meal.

§ 137.300 Farina.

(a) Farina is the food prepared by grinding and bolting cleaned wheat, other than durum wheat and red durum wheat, to such fineness that, when tested by the method prescribed in paragraph (b)(2) of this section, it passes through a No. 20 sieve, but not more than 3 percent passes through a No. 100 sieve. It is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 0.6 percent. Its moisture content is not more than 15 percent.

(b) For the purposes of this section:

(1) Ash and moisture are determined by the methods therefor referred to in § 137.105(c).

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 20 and No. 100 sieves, having standard 8-inch full-height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the United States Department of Commerce, National Bureau of Standards. Fit a No. 20 sieve into a No. 100 sieve. Attach bottom pan to the No. 100 sieve. Pour 100 grams of the sample into the No. 20 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for 2 minutes. Weigh the material which fails to pass through the No. 20 sieve and the material which passes through the No. 100 sieve.

§ 137.305 Enriched farina.

(a) Enriched farina conforms to the definition and standard of identity prescribed for farina by § 137.300, except that:

(1) It contains in each pound not less than 2.0 milligrams and not more than 2.5 milligrams of thiamine, not less than 1.2 milligrams and not more than 1.5 milligrams of riboflavin, not less than 16.0 milligrams and not more than 20.0 milligrams of niacin or niacinamide, and not less than 13.0 milligrams of iron (Fe).

(2) Vitamin D may be added in such quantity that each pound of the finished enriched farina contains not less than 250 U.S.P. units of the optional ingredient vitamin D.

(3) Calcium may be added in such quantity that each pound of the finished enriched farina contains not less than 500 milligrams of the optional ingredient calcium (Ca).

(4) It may contain not more than 8 percent by weight of the optional ingredient wheat germ or partly defatted wheat germ.

(5)(i) It may contain not less than 0.5 percent and not more than 1 percent by weight of the optional ingredient disodium phosphate; or

(ii) It may be treated with one of the proteinase enzymes papain or pepsin to reduce substantially the time required for cooking. In such treatment papain or pepsin, in an amount not to exceed 0.1 percent by weight, is added to the farina, which is moistened, warmed, and subsequently heated sufficiently to inactivate the enzyme and to dry the product to comply with the limit for moisture prescribed by § 137.300(a).

(6) In determining whether the ash content complies with the requirements of this section allowance is made for ash resulting from any added iron or salts of iron or calcium, or from any added disodium phosphate, or from any added wheat germ or partly defatted wheat germ.

Iron and calcium may be added only in forms which are harmless and assimilable. Dried irradiated yeast may be used as a source of vitamin D. The substances referred to in paragraphs (a)(1) and (2) of this section may be added in a harmless carrier which does not impair the enriched farina; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the farina.

(b)(1) All optional ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(2)(i) When the optional ingredient disodium phosphate is used, the label shall bear the statement "Disodium phosphate added for quick cooking".

(ii) When the proteinase enzyme treatment is used, the label shall bear the statement "Enzyme treated for quicker cooking".

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed by paragraph (b)(2) of this section shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter; except that where the name of the food is a part of a trademark or brand, then other written, printed, or graphic matter that is also a part of the trademark or brand may so intervene, if such statement is in such juxtaposition with the trademark or brand as to be conspicuously related to the name of the food.

§ 137.320 Semolina.

(a) Semolina is the food prepared by grinding and bolting cleaned durum wheat to such fineness that, when tested by the method prescribed in § 137.300(b)(2), it passes through a No. 20 sieve, but not more than 3 percent passes through a No. 100 sieve. It is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 0.92 percent. Its moisture content is not more than 15 percent.

(b) For the purpose of this section, ash and moisture are determined by the methods therefor referred to in § 137.105(c).

§ 137.350 Enriched rice.

(a) The foods for which definitions and standards of identity are prescribed by this section are forms of milled rice (except rice coated with talc and glucose and known as coated rice), to which nutrients have been added so that each pound of the rice contains:

(1) Not less than 2.0 milligrams and not more than 4.0 milligrams of thiamine; not less than 1.2 milligrams and not more than 2.4 milligrams of riboflavin; not less than 16 milligrams and not more than 32 milligrams of niacin or niacinamide; and not less than 13 milligrams and not more than 26 milligrams of iron (Fe).

(2) Each pound may contain not less than 250 U.S.P. units and not more than 1,000 U.S.P. units of vitamin D.

(3) Each pound may contain not less than 500 milligrams and not more than 1,000 milligrams of calcium (Ca). Calcium carbonate derived from the use of this substance in milling rice, when present in quantities that furnish less than 500 milligrams of calcium (Ca) per pound, is considered a normal ingredient of the milled rice used and not an optional ingredient of the enriched rice unless such enriched rice is labeled to show it contains the optional ingredient calcium. Iron and calcium may be added only in forms that are harmless and assimilable. The vitamins referred to in paragraphs (a)(1) and (2) of this section may be combined with harmless substances to render them insoluble in water, if the water-insoluble products are assimilable.

(4) In the case of enriched parboiled rice, butylated hydroxytoluene may be added as an optional ingredient in an amount not to exceed 0.0033 percent by weight of the finished food.

(b) The substances referred to in paragraph (a)(1), (2), and (3) of this section may be added in a harmless carrier. Such carrier is used only in the quantity necessary to effect an intimate and uniform mixture of such substances with the rice.

(c) Unless the label of the food bears the statement "To retain vitamins do not rinse before or drain after cooking" immediately preceding or following the name of the food and in letters not less than one-fourth the point size of type used for printing the name of the food (but in no case less than 8-point type) and the label bears no cooking directions calling for washing or draining or unless the food is precooked and it is packaged in consumer packages which are conspicuously and prominently labeled with directions for preparation which, if followed, will avoid washing away or draining off enriching ingredients, the substances named in paragraph (a) (1), (2), and (3) of this section shall be present in such quantity or in such form that when the enriched rice is washed as prescribed in paragraph (e) of this section, the washed rice contains not less than 85 percent of the minimum quantities of the substances named in paragraph (a) (1) of this section, as required for enriched rice; and in case any optional ingredients named in paragraph (a) (2) and (3) of this section are used, the washed rice also contains not less than 85 percent of the minimum quantity specified for the substance or substances used.

(d) The name specified for each food for which a definition and standard of identity is prescribed by this section is the common name of the kind of milled rice to which the enriching substances are added, preceded by the word "enriched" as, for example, "Enriched rice" or "Enriched parboiled rice".

(e) The method referred to in paragraph (c) of this section is as follows: Mix the contents of one or more containers and transfer ½ pound thereof to a 4-liter flask containing 2 liters of distilled water at room temperature (but not below 20° C). Stopper the flask and swirl it moderately for ½ minute so that the rice is in motion and in uniform suspension. Allow the rice to settle for ½ minute, then pour off 1,600 milliliters of the water, together with any floating and suspended matter, and discard. To the contents of the flask, add 1,600 milliliters of distilled water and 20 milliliters of 10 *N* hydrochloric acid. Agitate vigorously and wash down the sides of the flask with 150 milliliters of 0.1 *N* hydrochloric acid. In order to avoid excess foaming during the extraction, heat the mixture slowly to about 100° C, agitate agently if necessary, and maintain at this temperature until air is expelled. Again wash down the sides of the flask with 150 milliliters of 0.1 *N* hydrochloric acid. Heat the mixture in an autoclave at 120° C to 123° C for 30 minutes, remove and cool to room temperature. Dilute the mixture with distilled water so that the total volume is 2,500 milliliters. Swirl the flask, and while the solids are in uniform suspension pour off about 250 milliliters of the mixture for later determination of iron (and calcium, if this is to be determined). With filter paper that has been shown not to adsorb thiamine, riboflavin, or niacin, filter enough of the remaining mixture for determination of thiamine, riboflavin, and niacin. (In the case of a mixture difficult to filter, centrifuging or filtering through fritted glass, or both, using a suitable analytical filter-aid, may be substituted for, or may precede, filtering through paper.) Dilute an aliquot of filtrate with 0.1 *N* hydrochloric acid, so that each milliliter contains about 0.2 microgram of thiamine, and determine thiamine by the method entitled "Rapid Fluorometric Method—Official," beginning with section 38.32 of the book "Official Methods of Analysis of the Association of Official Agricultural Chemists," 8th Edition, 1955. [Ed. note, 10th edition, 1965, p. 761, sec. 39.028.] With a suitable aliquot determine riboflavin by the method entitled "Fluorometric Method—Official" in the same book, beginning with the third sentence of the second paragraph in section 38.35(a), "Adjust, with vigorous agitation * * *." [Ed. note, 10th edition, 1965, p. 762, sec. 39.035.] Determine niacin in a 200-milliliter aliquot of the filtrate by the method entitled "Chemical Method—Official" in the same book, beginning in the second sentence of the first paragraph in section 38.47 (a), "adjust to pH 4.5 with * * *." [Ed. note, 10th edition, 1965, p. 763, sec. 39.038.] Evaporate to dryness a 100-milliliter aliquot of the nonfiltered material withdrawn while agitating, and determine iron using the method on page 208 of the same book entitled "Iron—Official," [Ed. note, 10th edition, 1965, p. 192, secs. 13.011–13.013] and, if required, determine calcium as directed, on page 209 of the same book, entitled "Calcium—Official." [Ed. note, 10th edition, 1965, p. 193, sec. 13.014.]

(f) When the optional ingredient specified in paragraph (a) (4) of this section is added, the statement "Butylated hydroxytoluene added as a preservative" shall be placed on the label prominently and with such conspicuousness (as compared with other words, statements, designs, or devices in the label) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase.

NOTE: The Order of the Commissioner of Food and Drugs appearing at 23 F.R. 1170, Feb. 25, 1958, amending paragraphs (a) (1) and (c) provides in part as follows: The regulations in § 137.350 (formerly § 15.525) are stayed insofar as they require each pound of the food to contain not less than 1.2 milligrams and not more than 2.4 milligrams of riboflavin. This stay shall continue until final action is taken disposing of the objections, after public hearing thereon.

PART 139—MACARONI AND NOODLE PRODUCTS

Subpart A—[Reserved]

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AUTHORITY: Secs. 401, 701, 52 Stat. 1046, as amended, 1055–1056, as amended (21 U.S.C. 341, 371).

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Macaroni and Noodle Products

§ 139.110 Macaroni products.

(a) Macaroni products are the class of food each of which is prepared by drying formed units of dough made from semolina, durum flour, farina, flour, or any combination of two or more of these, with water and with or without one or more of the optional ingredients specified in paragraphs (a) (1) to (6), inclusive, of this section.

(1) Egg white, frozen egg white, dried egg white, or any two or all of these, in such quantity that the solids thereof are not less than 0.5 percent and not more than 2.0 percent of the weight of the finished food.

(2) Disodium phosphate, in a quantity not less than 0.5 percent and not more than 1.0 percent of the weight of the finished food.

(3) Onions, celery, garlic, bay leaf, or any two or more of these, in a quantity which seasons the food.

(4) Salt, in a quantity which seasons the food.

(5) Gum gluten, in such quantity that the protein content of the finished food is not more than 13 percent by weight. The finished macaroni product contains not less than 87 percent of total solids as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fifth edition, 1940, page 235 [Ed. note, 10th edition, 1965, p. 209, sec. 13.115], under "Vacuum Oven Method—Official."

(6) Concentrated glyceryl monostearate (containing not less than 90 percent monoester), in a quantity not exceeding 2 percent by weight of the finished food.

(b) Macaroni is the macaroni product the units of which are tube-shaped and more than 0.11 inch but not more than 0.27 inch in diameter.

(c) Spaghetti is the macaroni product the units of which are tube-shaped or cord-shaped (not tubular) and more than 0.06 inch but not more than 0.11 inch in diameter.

(d) Vermicelli is the macaroni product the units of which are cord-shaped (not tubular) and not more than 0.06 inch in diameter.

(e) The name of each food for which a definition and standard of identity is prescribed by this section is "Macaroni product"; or alternatively, the name is "Macaroni", "Spaghetti", or "Vermi-

celli", as the case may be, when the units of the food are of the shapes and sizes specified in paragraph (b), (c), or (d), respectively, of this section.

(f) (1) When disodium phosphate is used the label shall bear the statement "Disodium phosphate added for quick cooking".

(2) When any ingredient specified in paragraph (a) (3) of this section is used the label shall bear the statement "Seasoned with _____", the blank being filled in with the common name of the ingredient; or in the case of bay leaves the statement "Spiced", "Spice added", or "Spiced with bay leaves".

(3) When the ingredient specified in paragraph (a) (6) of this section is used, the label shall bear the statement "Glyceryl monostearate added" or the statement "With added glyceryl monostearate".

(4) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed in this section, showing the optional ingredients used, shall immediately and conspicuously precede or follow, or in part precede and in part follow, such name, without intervening written, printed, or graphic matter.

§ 139.115 Enriched macaroni products.

(a) Enriched macaroni products are the class of food each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of optional ingredients, prescribed for macaroni products by § 139.110 (a) and (f), except that:

(1) Each such food contains in each pound not less than 4 mg. and not more than 5 mg. of thiamine, not less than 1.7 mg. and not more than 2.2 mg. of riboflavin, not less than 27 mg. and not more than 34 mg. of niacin or niacinamide, and not less than 13 mg. and not more than 16.5 mg. of iron (Fe);

(2) Each such food may also contain as an optional ingredient added vitamin D in such quantity that each pound of the finished food contains not less than 250 U. S. P. units and not more than 1000 U. S. P. units of vitamin D.

(3) Each such food may also contain as an optional ingredient added calcium in such quantity that each pound of the finished food contains not less than 500 mg. and not more than 625 mg. of calcium (Ca);

(4) Each such food may also contain as an optional ingredient partly defatted wheat germ but the amount thereof does not exceed 5 percent of the weight of the finished food;

(5) Each such food may be supplied, wholly or in part, with the prescribed quantity of any substance referred to in paragraphs (a) (1), (2), and (3) of this section through the use of dried yeast, dried torula yeast, partly defatted wheat germ, enriched farina, or enriched flour, or through the direct additions of any of the substances prescribed in paragraphs (a) (1), (2), and (3) of this section.

Iron and calcium may be added only in forms which are harmless and assimilable. The substances referred to in paragraphs (a) (1) and (2) of this section may be added in a harmless carrier which does not impair the enriched macaroni product, such carrier being used only in the quantity reasonably necessary to effect an intimate and uniform distribution of such substances in the finished enriched macaroni product.

(b) Enriched macaroni is the enriched macaroni product the units of which conform to the specifications of shape and size prescribed for macaroni by § 139.110(b).

(c) Enriched spaghetti is the enriched macaroni product the units of which conform to the specifications of shape and size prescribed for spaghetti by § 139.110(c).

(d) Enriched vermicelli is the enriched macaroni product the units of which conform to the specifications of shape and size prescribed for vermicelli by § 139.110(d).

(e) The name of each food for which a definition and standard of identity is prescribed by this section is "Enriched Macaroni product"; or alternatively, the name is "Enriched macaroni", "Enriched spaghetti", or "Enriched vermicelli", as the case may be, when the units of the food comply with the requirements of paragraphs (b), (c), or (d) respectively of this section.

§ 139.117 Enriched macaroni products with fortified protein.

(a) (1) Each of the foods for which a standard of identity is prescribed by this section is produced by drying formed units of dough made with one or more of the milled wheat ingredients designated in §§ 139.110(a) and 139.138(a), and other ingredients to enable the finished food to meet the protein requirements set out in paragraph (a) (2) (i) of this section. Edible protein sources, including food grade flours or meals made from nonwheat cereals or from oilseeds, may be used. Vitamin and mineral enrichment nutrients are added to bring the food into conformity with the requirements of paragraph (b) of this section. Safe and suitable ingredients, as provided for in paragraph (c) of this section, may be added. The proportion of the milled wheat ingredient is larger than the proportion of any other ingredient used.

(2) Each such finished food, when tested by the methods described in the cited sections of the book "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th edition, 1970, meets the following specifications:

(i) The protein content (N×6.25) is not less than 20 percent by weight (on a 13 percent moisture basis) as determined by the method in section 14.134. The protein quality is not less than 95 percent that of casein as determined on the cooked food by the method in sections 39.166 through 39.170 of the official methods.

(ii) The total solids content is not less than 87 percent by weight as determined by the method in section 14.125 of the official methods.

(b) (1) Each food covered by this section contains in each pound 5 milligrams of thiamin, 2.2 milligrams of riboflavin, 34 milligrams of niacin or niacinamide, and 16.5 milligrams of iron.

(2) Each pound of such food may also contain 625 milligrams of calcium.

(3) Iron and calcium may be added only in forms which are harmless and assimilable. The enrichment nutrients may be added in a harmless carrier used only in a quantity necessary to effect a uniform distribution of the nutrients in the finished food. The requirements of paragraphs (b) (1) and (2) of this section shall be deemed to have been met if reasonable overages, within the limits of good manufacturing practice, are present to assure that the prescribed levels of the vitamins and mineral(s) are maintained throughout the expected shelf life of the food under customary conditions of distribution.

(c) The safe and suitable ingredients referred to in paragraph (a) of this section are ingredients that serve a useful purpose, e.g., to fortify the protein or facilitate production of the food, but they do not include color additives, artificial flavorings, artificial sweeteners, chemical preservatives, or starches. Ingredients deemed suitable for use by this paragraph are added in amounts that are not in excess of those reasonably required to achieve their intended purposes. Ingredients are deemed to be safe if they are not food additives within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act, or in case they are food additives, if they are used in conformity with regulations established pursuant to section 409 of the act.

(d) (1) The name of any food covered by this section is "Enriched Wheat _____ Macaroni Product—with Fortified Protein", the blank being filled in with appropriate word(s) such as "Soy" to show the source of any flours or meals used that were made from nonwheat cereals or from oilseeds. In lieu of the words "Macaroni Product" the word "Macaroni", "Spaghetti", or "Vermicelli", as appropriate, may be used if the units conform in shape and size to the requirements of § 139.110 (b), (c), or (d).

(2) When any ingredient, not designated in the part of the name prescribed in paragraph (d) (1) of this section, is added in such proportion as to contribute 10 percent or more of the quantity of protein contained in the finished food, the name shall include the statement "Made with _____", the blank being filled in with the name of each such ingredient, e.g., "Made with nonfat milk".

(3) When, in conformity with paragraph (d) (1) or (2) of this section, two or more ingredients are listed in the name, their designations shall be arranged in descending order of predominance by weight.

(4) In the case of a food made to comply with another section of this part, but which also meets the compositional requirements of this section, it may alternatively bear the name set out in that other section.

(e) The common name of each of the ingredients used shall be declared on the label as required by the applicable section of Part 101 of this chapter. Further, the declaration of ingredients as set forth in this paragraph, shall appear in letters not less than one-half the size of that required by § 101.105 of this chapter for the declaration of net quantity of contents, and in no case less than one-sixteenth of an inch in height.

§ 139.120 Milk macaroni products.

(a) Milk macaroni products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for macaroni products by § 139.110 (a) and (f) (2) and (3), except that:

(1) Milk is used as the sole moistening ingredient in preparing the dough; or in lieu of milk one or more of the milk ingredients specified in paragraph (f) of this section is used, with or without water, in such quantity that the weight of milk solids therein is not less than 3.8 percent of the weight of the finished milk macaroni product; and

(2) None of the optional ingredients permitted by § 139.110(a) (1) and (2) is used. When the optional ingredient gum gluten (§ 139.110(a)(5)) is added, the quantity is such that the protein derived therefrom, together with the protein derived from semolina, durum flour, farina, flour, or any combination of these used, does not exceed 13 percent of the weight of the finished food.

(b) Milk macaroni is the milk macaroni product the units of which conform to the specifications of shape and size prescribed for macaroni by § 139.110 (b).

(c) Milk spaghetti is the milk macaroni product the units of which conform to the specifications of shape and size prescribed for spaghetti by § 139.110 (c).

(d) Milk vermicelli is the milk macaroni product the units of which conform to the specifications of shape and size prescribed for vermicelli by § 139.110 (d).

(e) The name of each food for which a definition and standard of identity is prescribed by this section is "Milk Macaroni Product"; or alternatively, the name is "Milk macaroni", "Milk spaghetti", or "Milk vermicelli", as the case may be, when the units of the food comply with the requirements of paragraph (b), (c), or (d), respectively, of this section.

(f) The milk ingredients referred to in paragraph (a)(1) of this section are concentrated milk, evaporated milk, dried milk, and a mixture of butter with skim milk, concentrated skim milk, evaporated skim milk, nonfat dry milk (dried skim milk), or any two or more of these, in such proportion that the weight of nonfat milk solids in such mixture is not more than 2.275 times the weight of milk fat therein.

§ 139.121 Nonfat milk macaroni products.

(a) Each of the macaroni products made with nonfat milk for which a definition and standard of identity is prescribed by this section conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for macaroni products by § 139.110 (a) and (f) (2), (3), and (4), except that:

(1) (i) In preparing the dough, nonfat dry milk or concentrated skim milk, or a mixture of these, is used in an amount such that the finished macaroni product made with nonfat milk contains by weight not less than 12 percent and not more than 25 percent of milk solids-not-fat. Carrageenan or salts of carrageenan conforming to the requirements of § 172.620 and § 172.626 of this chapter may be used in a quantity not in excess of 0.833 percent by weight of the milk solids-not-fat used.

(ii) When the ingredient carrageenan or the salts of carrageenan specified in paragraph (a)(1)(i) of this section is used, the label shall bear the statement, "Carrageenan added" or "Salts of carrageenan added" or the statement "With added carrageenan" or "With added salts of carrageenan", in the manner further prescribed by § 139.110(f)(4).

(2) None of the optional ingredients permitted by § 139.110(a) (1), (2), and (5) are used.

(b) The name of each food for which a definition and standard of identity is prescribed by this section is "Macaroni products made with nonfat milk" or, alternatively, the name is "Macaroni made with nonfat milk", "Spaghetti made with nonfat milk", or "Vermicelli made with nonfat milk", as the case may be when the units of the food conform to the specifications of shape and size prescribed by § 139.110 (b), (c), or (d), respectively.

§ 139.122 Enriched nonfat milk macaroni products.

(a) Each of the enriched macaroni products made with nonfat milk for which a definition and standard of identity is prescribed by this section conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for macaroni products by § 139.110 (a) and (f) (2), (3), and (4), except that:

(1) (i) In preparing the dough, nonfat dry milk or concentrated skim milk, or a mixture of these, is used in an amount such that the finished enriched macaroni product made with nonfat milk contains by weight not less than 12 percent and not more than 25 percent of milk solids-not-fat. Carrageenan or the salts of carrageenan conforming to the requirements of § 172.620 and § 172.626 of this chapter may be used in a quantity not in excess of 0.833 percent by weight of the milk solids-not-fat used.

(ii) When the ingredient carrageenan or the salts of carrageenan specified in paragraph (a)(1)(i) of this section is used, the label shall bear the statement, "Carrageenan added" or "Salts of carrageenan added" or the statement "With added carrageenan" or "With added salts of carrageenan", in the manner further prescribed by § 139.110(f)(4).

(2) None of the optional ingredients permitted by § 139.110(a) (1), (2), and (5) are used.

(3) Each such food contains in each pound not less than 4 milligrams and not more than 5 milligrams of thiamine, not less than 1.7 milligrams and not more than 2.2 milligrams of riboflavin, not less than 27 milligrams and not more than 34 milligrams of niacin or niacinamide, and not less than 13 milligrams and not more than 16.5 milligrams of iron (Fe). These substances may be added through direct addition or wholly or in part through the use of dried yeast, dried torula yeast, partly defatted wheat germ (as provided for in paragraph (a)(4) of this section), enriched farina, or enriched flour. They may be added in a harmless carrier, such carrier being used only in the quantity reasonably necessary to effect an intimate and uniform distribution of such substances in the finished food. Iron may be added only in a form that is harmless and assimilable.

(4) Each such food may also contain as an optional ingredient partly defatted wheat germ, but the amount thereof does not exceed 5 percent by weight of the finished food.

(b) The name of each food for which a definition and standard of identity is prescribed by this section is "Enriched macaroni product made with nonfat milk" or, alternatively, the name is "Enriched macaroni made with nonfat milk", "Enriched spaghetti made with nonfat milk", or "Enriched vermicelli made with nonfat milk," as the case may be when the units of the food conform to the specifications of shape and size prescribed by § 139.110 (b), (c), or (d), respectively.

§ 139.125 Vegetable macaroni products.

(a) Vegetable macaroni products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for macaroni products by § 139.110 (a) and (f) (2) and (3), except that:

(1) Tomato (of any red variety), artichoke, beet, carrot, parsley, or spinach is added in such quantity that the solids thereof is not less than 3 percent by weight of the finished vegetable macaroni product (the vegetable used may be fresh, canned, dried, or in the form of puree or paste); and

(2) None of the optional ingredients permitted by § 139.110(a) (1) and (2) is used. When the optional ingredient gum gluten (§ 139.110(a)(5)) is added, the quantity is such that the protein derived therefrom, together with the protein de-

rived from the semolina, durum flour, farina, flour or any combination of these used, does not exceed 13 percent of the weight of the finished food.

(b) Vegetable macaroni is the vegetable macaroni product the units of which conform to the specifications of shape and size prescribed for macaroni by § 139.110(b).

(c) Vegetable spaghetti is the vegetable macaroni product the units of which conform to the specifications of shape and size prescribed for spaghetti by § 139.110(c).

(d) Vegetable vermicelli is the vegetable macaroni product, the units of which conform to the specifications of shape and size prescribed for vermicelli by § 139.110(d).

(e) The name of each food for which a definition and standard of identity is prescribed by this section is "_____ macaroni product", the blank being filled in with the name whereby the vegetable used is designated in paragraph (a) of this section; or alternatively, the name is "_____ macaroni", "_____ spaghetti", or "_____ vermicelli", as the case may be, when the units of the food comply with the requirements of paragraph (b), (c), or (d), respectively, the blank in each instance being filled in with the name whereby the vegetable used is designated in paragraph (a) of this section.

§ 139.135 Enriched vegetable macaroni products.

(a) Each of the macaroni products for which a definition and standard of identity is prescribed by this section conforms to the definition and standard of identity and is subject to the requirements for label statement of optional ingredients prescribed for macaroni products by § 139.110 (a) and (f), and in addition is enriched to meet the requirements prescribed for enriched macaroni products by § 139.115 and contains a vegetable ingredient in compliance with the requirements prescribed for vegetable macaroni products by § 139.125.

(b) The name of each food for which a definition and standard of identity is prescribed by this section is "Enriched _____ macaroni product", or, alternatively, the name is "Enriched _____ macaroni", "Enriched _____ spaghetti", or "Enriched _____ vermicelli", when the units comply with the shape and size requirements prescribed for macaroni, spaghetti, or vermicelli in § 139.110 (b), (c), or (d). The blank in each instance is filled in with the name of the vegetable used, as specified in § 139.125(a). For example, the name of an enriched macaroni product containing the prescribed amount of spinach and made in units not conforming in shape and size to the requirements for macaroni, spaghetti, or vermicelli is "Enriched spinach macaroni product".

§ 139.138 Whole wheat macaroni products.

(a) Whole wheat macaroni products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for macaroni products by § 139.110 (a) and (f) (2) and (3), except that:

(1) Whole wheat flour or whole durum wheat flour or both are used as the sole wheat ingredient; and

(2) None of the optional ingredients permitted by § 139.110 (a) (1), (2), and (5) is used.

(b) Whole wheat macaroni is the whole wheat macaroni product the units of which conform to the specifications of shape and size prescribed for macaroni by § 139.110(b).

(c) Whole wheat spaghetti is the whole wheat macaroni product the units of which conform to the specifications of shape and size prescribed for spaghetti by § 139.110(c).

(d) Whole wheat vermicelli is the whole wheat macaroni product the units of which conform to the specifications of shape and size prescribed for vermicelli by § 139.110(d).

(e) The name of each food for which a definition and standard of identity is prescribed by this section is "Whole wheat macaroni product"; or alternatively, the name is "Whole wheat macaroni", "Whole wheat spaghetti", or "Whole wheat vermicelli", as the case may be, when the units of the food comply with the requirements of paragraph (b), (c), or (d), respectively, of this section.

§ 139.140 Wheat and soy macaroni products.

(a) Wheat and soy macaroni products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for macaroni products by § 139.110 (a) and (f) (2) and (3), except that:

(1) Soy flour is added in a quantity not less than 12.5 percent of the combined weight of the wheat and soy ingredients used (the soy flour used is made from heat-processed, dehulled soybeans, with or without the removal of fat therefrom); and

(2) None of the optional ingredients permitted by § 139.110(a) (1) and (2) is used. When the optional ingredient gum gluten (§ 139.110(a)(5)) is added, the quantity is such that the protein derived therefrom, together with the protein derived from semolina, durum flour, farina, flour or any combination of these used, does not exceed 13 percent of the weight of the finished food.

(b) Wheat and soy macaroni is the wheat and soy macaroni product the units of which conform to the specifications of shape and size prescribed for macaroni by § 139.110(b).

(c) Wheat and soy spaghetti is the wheat and soy macaroni product the units of which conform to the specifications of shape and size prescribed for spaghetti by § 139.110(c).

(d) Wheat and soy vermicelli is the wheat and soy macaroni product the units of which conform to the specifications of shape and size prescribed for vermicelli by § 139.110(d).

(e) The name of each food for which a definition and standard of identity is prescribed by this section is "Wheat and soy macaroni product", "Wheat and soybean macaroni product", "_____ and soy macaroni product", or "_____ and soybean macaroni product", the blank in each instance being filled in with the name whereby the wheat ingredient used is designated in § 139.110 (a); or alternatively, the name is "Wheat and soy macaroni", "Wheat and soybean macaroni", "_____ and soy macaroni", or "_____ and soybean macaroni" when the units of the food comply with the requirements of paragraph (b) of this section; or "Wheat and soy spaghetti", "Wheat and soybean spaghetti", "_____ and soy spaghetti", or "_____ and soybean spaghetti" when such units comply with the requirements of paragraph (c) of this section; or "Wheat and soy vermicelli", "Wheat and soybean vermicelli", "_____ and soy vermicelli", or "_____ and soybean vermicelli" when such units comply with the requirements of paragraph (d) of this section, the blank in each instance being filled in with the name whereby the wheat ingredient used is designated in § 139.110(a).

§ 139.150 Noodle products.

(a) Noodle products are the class of food each of which is prepared by drying formed units of dough made from semolina, durum flour, farina, flour, or any combination of two or more of these, with liquid eggs, frozen eggs, dried eggs, egg yolks, frozen yolks, dried yolks, or any combination of two or more of these, with or without water and with or without one or more of the optional ingredients specified in paragraph (a) (1) to (4) of this section inclusive:

(1) Onions, celery, garlic, bay leaf, or any two or more of these, in a quantity which seasons the food.

(2) Salt, in a quantity which seasons the food.

(3) Gum gluten, in such quantity that the protein derived therefrom, together with the protein derived from semolina, durum flour, farina, flour or any combination of these used, does not exceed 13 percent of the weight of the finished food.

(4) Concentrated glyceryl monostearate (containing not less than 90 percent monoester) in a quantity not exceeding 2 percent by weight of the finished food. The finished noodle product contains not less than 87 percent of total solids as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fifth Edition, 1940, page 235 [Ed. note, 10th edition, 1965, p. 209, sec. 13.115], under "Vacuum Oven Method—Official." The total solids of noodle products contains not less than 5.5 percent by weight of the solids of egg, or egg yolk.

(b) Noodles, egg noodles, is the noodle product the units of which are ribbon-shaped.

(c) Egg macaroni is the noodle product the units of which are tube-shaped and more than 0.11 inch but not more than 0.27 inch in diameter.

(d) Egg spaghetti is the noodle product the units of which are tube-shaped or cord-shaped (not tubular) and more than 0.06 inch but not more than 0.11 inch in diameter.

(e) Egg vermicelli is the noodle product the units of which are cord-shaped (not tubular) and not more than 0.06 inch in diameter.

(f) The name of each food for which a definition and standard of identity is prescribed by this section is "Noodle product" or "Egg noodle product"; or alternatively, the name is "Noodles" or "Egg noodles", "Egg macaroni", "Egg spaghetti", or "Egg vermicelli", as the case may be, when the units of the food are of the shapes and sizes specified in paragraph (b), (c), (d), or (e), respectively, of this section.

(g)(1) When any ingredient specified in paragraph (a)(1) of this section is used, the label of the noodle product shall bear the statement "Seasoned with ----------", the blank being filled in with the common name of the ingredient; or in the case of bay leaves, the statement "Spiced", "Spice added", or "Spiced with bay leaves".

(2) When the ingredient specified in paragraph (a)(4) of this section is used, the label shall bear the statement "Glyceryl monostearate added" or the statement "With added glyceryl monostearate".

(h) Wherever the name of the food appears on such label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed in this section, showing the ingredients used shall immediately and conspicuously precede or follow, or in part precede and in part follow, such name without intervening written, printed, or other graphic matter.

§ 139.155 Enriched noodle products.

(a) Enriched noodle products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for noodle products by § 139.150 (a) and (g), except that:

(1) Each such food contains in each pound not less than 4 mg. and not more than 5 mg. of thiamine, not less than 1.7 mg. and not more than 2.2 mg. of riboflavin, not less than 27 mg. and not more than 34 mg. of niacin or niacinamide, and not less than 13 mg. and not more than 16.5 mg. of iron (Fe);

(2) Each such food may also contain as an optional ingredient added vitamin D in such quantity that each pound of the finished food contains not less than 250 U.S.P. units and not more than 1000 U.S.P. units of vitamin D;

(3) Each such food may also contain as an optional ingredient added calcium in such quantity that each pound of the finished food contains not less than 500 mg. and not more than 625 mg. of calcium (Ca);

(4) Each such food may also contain as an optional ingredient partly defatted wheat germ, but the amount thereof does not exceed 5 percent of the weight of the finished food;

(5) Each such food may be supplied, wholly or in part, with the prescribed quantity of any substance referred to in paragraphs (a) (1), (2), and (3) of this section through the use of dried yeast, dried torula yeast, partly defatted wheat germ, enriched farina, or enriched flour, or through the direct additions of any of the substances prescribed in paragraphs (a) (1), (2), and (3) of this section.

Iron and calcium may be added only in forms which are harmless and assimilable. The substances referred to in paragraph (a) (1) and (2) of this section may be added in a harmless carrier which does not impair the enriched noodle product, such carrier being used only in the quantity reasonably necessary to effect an intimate and uniform distribution of such substances in the finished enriched noodle product.

(b) Enriched noodles, enriched egg noodles are the enriched noodle products the units of which conform to the specifications of shape and size prescribed for noodles in § 139.150(b).

(c) Enriched egg macaroni is the enriched noodle product the units of which conform to the specifications of shape and size prescribed for egg macaroni in § 139.150 (c).

(d) Enriched egg spaghetti is the enriched noodle product the units of which conform to the specifications of shape and size prescribed for egg spaghetti in § 139.150 (d).

(e) Enriched egg vermicelli is the enriched noodle product the units of which conform to the specifications of shape and size prescribed for egg vermicelli in § 139.150(e).

(f) The name of each food for which a definition and standard of identity is prescribed by this section is "Enriched noodle product" or "Enriched egg noodle product"; or alternatively, the name is "Enriched noodles", or "Enriched egg noodles", "Enriched egg macaroni", "Enriched egg spaghetti", or "Enriched egg vermicelli", as the case may be, when the units of the food comply with the requirements of paragraphs (b), (c), (d), or (e) respectively of this section.

§ 139.160 Vegetable noodle products.

(a) Vegetable noodle products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for noodle products by § 139.150 (a) and (g), except that tomato (of any red variety), artichoke, beet, carrot, parsley, or spinach is added in such quantity that the solids thereof is not less than 3 percent by weight of the finished vegetable noodle product (the vegetable used may be fresh, canned, dried, or in the form of puree or paste).

(b) Vegetable noodles, vegetable egg noodles, is the vegetable noodle product the units of which are ribbon-shaped.

(c) Vegetable egg macaroni is the vegetable noodle product the units of which conform to the specifications of shape and size prescribed for egg macaroni by § 139.150 (c).

(d) Vegetable egg spaghetti is the vegetable noodle product the units of which conform to the specifications of shape and size prescribed for egg spaghetti by § 139.150 (d).

(e) Vegetable egg vermicelli is the vegetable noodle product the units of which conform to the specifications of shape and size prescribed for egg vermicelli by § 139.150 (e).

(f) The name of each food for which a definition and standard of identity is prescribed by this section is "---------- noodle product" or "-------- egg noodle product", the blank being filled in with the name whereby the vegetable used is designated in paragraph (a) of this section; or alternatively, the name is "----- noodles" or "------ egg noodles", "-------- egg macaroni", "------ --egg spaghetti", or "------ egg vermicelli", as the case may be, when the units of the food comply with the requirements of paragraph (b), (c), (d), or (e) of this section, respectively, the blank in each instance being filled in with the name whereby the vegetable is designated in paragraph (a) of this section.

§ 139.165 Enriched vegetable noodle products.

(a) Each of the noodle products for which a definition and standard of identity is prescribed by this section conforms to the definition and standard of identity and is subject to the requirements for label declaration of optional ingredients prescribed for noodle products by § 139.150 (a), (g), and (h), and in addition is enriched to meet the requirements prescribed for enriched noodle products by § 139.155 and, except as hereinafter provided, contains a vegetable ingredient in compliance with the requirements prescribed for vegetable noodle products by § 139.160. Carrots, because they are apt to impart an egg-yolk color, are not used in enriched vegetable noodle products.

(b) The name of each food for which a definition and standard of identity is prescribed by this section is "Enriched ---------- noodle product", "Enriched ---------- egg noodle product", or, alternatively, the name is "Enriched ---------- noodles", or "Enriched ---------- egg noodles", "Enriched ---------- egg macaroni", "Enriched ---------- egg spaghetti", or "Enriched ---------- egg vermicelli", when the units comply with the size and shape requirements for noodles, macaroni, spaghetti, or vermicelli in § 139.150 (b), (c), (d), or (e). The blank in each instance is filled in with the name of the vegetable used, as specified in § 139.160(a).

§ 139.180 Wheat and soy noodle products.

(a) Wheat and soy noodle products are the class of food each of which conforms to the definition and standard of identity, and is subject to the require-

ments for label statement of optional ingredients, prescribed for noodle products by § 139.150 (a) and (g), except that soy flour is added in a quantity not less than 12.5 percent of the combined weight of the wheat and soy ingredients used (the soy flour used is made from heat-processed, dehulled soybeans, with or without the removal of fat therefrom).

(b) Wheat and soy noodles, wheat and soy egg noodles, is the wheat and soy noodle product the units of which are ribbon-shaped.

(c) Wheat and soy egg macaroni is the wheat and soy noodle product the units of which conform to the specifications of shape and size prescribed for egg macaroni by § 139.150 (c).

(d) Wheat and soy egg spaghetti is the wheat and soy noodle product the units of which conform to the specifications of shape and size prescribed for egg spaghetti by § 139.150 (d).

(e) Wheat and soy egg vermicelli is the wheat and soy noodle product the units of which conform to the specifications of shape and size prescribed for egg vermicelli by § 139.150 (e).

(f) The name of each food for which a definition and standard of identity is prescribed by this section is "Wheat and soy noodle product", "Wheat and soy egg noodle product", "Wheat and soybean noodle product", "Wheat and soybean egg noodle product", "_____ and soy noodle product", "_____ and soy egg noodle product", "_____ and soybean noodle product", or "_____ and soybean egg noodle product", the blank in each instance being filled in with the name whereby the wheat ingredient used is designated in § 139.150(a); or alternatively, the name is "Wheat and soy noodles", "Wheat and soy egg noodles", "Wheat and soybean noodles", "Wheat and soybean egg noodles", "_____ and soy noodles", "_____ and soy egg noodles", "_____ and soybean noodles", or "_____ and soybean egg noodles" when the units of the food comply with the requirements of paragraph (b) of this section; or "Wheat and soy egg macaroni", "Wheat and soybean egg macaroni", "_____ and soy egg macaroni", or "_____ and soybean egg macaroni" when such units comply with the requirements of paragraph (c) of this section; or "Wheat and soy egg spaghetti", "Wheat and soybean egg spaghetti", "_____ and soy egg spaghetti", or "_____ and soybean egg spaghetti" when such units comply with the requirements of paragraph (d) of this section; or "Wheat and soy egg vermicelli", "Wheat and soybean egg vermicelli", "_____ and soy egg vermicelli", or "_____ and soybean egg vermicelli", when such units comply with the requirements of paragraph (e) of this section, the blank in each instance being filled in with the name whereby the wheat ingredient used is designated in § 139.150(a).

PART 145—CANNED FRUITS

Subpart A—General Provisions

Sec.
145.3 Definitions.

Subpart B—Requirements for Specific Standardized Canned Fruits

Sec.
145.110 Canned applesauce.
145.115 Canned apricots.
145.116 Artificially sweetened canned apricots.
145.118 Canned apricots with rum.
145.120 Canned berries.
145.125 Canned cherries.
145.126 Artificially sweetened canned cherries.
145.128 Canned cherries with rum.
145.130 Canned figs.
145.131 Artificially sweetened canned figs.
145.134 Canned preserved figs.
145.135 Canned fruit cocktail.
145.136 Artificially sweetened canned fruit cocktail.
145.140 Canned seedless grapes.
145.145 Canned grapefruit.
145.170 Canned peaches.
145.171 Artificially sweetened canned peaches.
145.173 Canned peaches with rum.
145.175 Canned pears.
145.176 Artificially sweetened canned pears.
145.178 Canned pears with rum.
145.180 Canned pineapple.
145.181 Artificially sweetened canned pineapple.
145.185 Canned plums.
145.190 Canned prunes.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046 as amended, 1055–1056 as amended (21 U.S.C. 341, 371) unless otherwise noted.

Subpart A—General Provisions

§ 145.3 Definitions.

For the purposes of this part:

(a) The term "corn sirup" means a clarified, concentrated aqueous solution of the products obtained by the incomplete hydrolysis of cornstarch, and includes dried corn sirup. The solids of corn sirup and of dried corn sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose.

(b) The term "dextrose" means the hydrated or anhydrous, refined monosaccharide obtained from hydrolyzed starch.

(c) The term "dried glucose sirup" means the product obtained by drying "glucose sirup."

(d) The term "glucose sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of glucose sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose.

(e) The term "invert sugar sirup" means an aqueous solution of inverted or partly inverted, refined or partly refined sucrose, the solids of which contain not more than 0.3 percent by weight of ash, and which is colorless, odorless, and flavorless, except for sweetness.

(f) The term "sugar" means refined sucrose.

(g) The terms "edible organic acid" and "edible organic salt" refer to any edible organic acid and any edible organic salt added for the purpose of flavor enhancement that either is not a food additive as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act or, if it is a food additive as so defined, is used in conformity with regulations established pursuant to section 409 of the act.

(h) The term "water" means, in addition to water, any mixture of water and fruit juice in which the fruit juice(s) is less than 50 percent of such mixture, including any water contributed by the use of liquid nutritive carbohydrate sweeteners.

(i) The term "fruit juice(s) and water" means any mixture of fruit juice as herein defined and water, including any water contributed by the use of liquid nutritive carbohydrate sweeteners, in which the fruit juice(s) is 50 percent, or more, of such mixture except that water used in preparing equivalent single strength juice(s) from concentrate(s) shall not be considered to be a mixture of fruit juice and water.

(j) The term "fruit juice(s)" means single strength expressed juice(s) of sound, mature fruit(s). It may be fresh, frozen, canned, or made from concentrate(s). However, if it is made from concentrate(s), the juice(s) shall be reconstituted with water to not less than the soluble solids that such fruit juice had before concentration. Fruit juice(s) may be used singly or in combination. If a fruit juice(s) is used which is regulated by a standard of identity of this chapter, it shall conform to the compositional requirements prescribed by such standard prior to the addition of any sweetener which may be used.

(k) The term "clarified juice" means the liquid expressed wholly or in part from fruit peelings, fruit shells, fruit cores, or from the fruit flesh or parts thereof, which is clarified and may be further refined or concentrated.

(l) The term "solid pack" means the product contains practically all fruit with only the very little free flowing liquid that is expressed from the fruit and to which no packing media have been added.

(m) The procedure for determining the densities of the packing media means the following: The density of the packing medium, when measured 15 days or more after packing, or the density of the blended homogenized slurry of the comminuted entire contents of the container, when measured less than 15 days after canning, is determined according to "Official Method of Analysis of the Association of Official Analytical Chemists", 11th Ed., 1970, p. 526, section 31.011 (Solids) "By Means of the Refractometer—Official, Final Action" (and 47.012 and 47.015)[3] with result expressed as percent by weight of sucrose (degrees Brix) with correction for temperature to the equivalent at 20° C, but without correction for invert sugar or other substances.

(n) The procedure for determining drained weight is as follows: Tilt the opened container so as to distribute the contents evenly over the meshes of a circular sieve which has previously been weighed. The diameter of the sieve is 20.3 centimeters (8 inches) if the quantity of contents of the container is less than 1.4 kilograms (3 pounds) and 30.5 centimeters (12 inches) if such quantity is 1.4 kilograms (3 pounds) or more. The bottom of the sieve is woven-wire cloth

which complies with the specifications for the No. 8 sieve set forth in the "Definitions of Terms and Explanatory Notes," p. xviii, of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.* Carefully invert by hand all fruits having cups or cavities if they fall on the sieve with cups or cavities up. Cups or cavities in soft products may be drained by tilting sieve. Without further shifting the material on the sieve, incline the sieve at an angle of 17° to 20° to facilitate drainage. Two minutes after the drainage begins, weigh the sieve and drained fruit. The weight so found, less the weight of the sieve, shall be considered to be the weight of the drained fruit.

(o) Compliance means the following: Unless otherwise provided in a standard, a lot of canned fruits shall be deemed in compliance for the following factors, to be determined by the sampling and acceptance procedure as provided in paragraph (p) of this section, namely:

(1) *Packing medium density.* A lot shall be deemed to be in compliance for packing medium density based on the average sucrose value for all samples analyzed according to the sampling plans, but no container may have a sucrose value lower than that of the next lower category or 2 percent by weight sucrose (degrees Brix) lower if no lower category exists.

(2) *Quality.* The quality of a lot shall be considered acceptable when the number of defectives does not exceed the acceptance number in the sampling plans.

(3) *Fill of container.* A lot shall be deemed to be in compliance for fill of container (packing medium and fruit ingredient) when the number of defectives does not exceed the acceptance number (c) in the sampling plans.

(4) *Drained weight.* A lot shall be deemed to be in compliance for drained weight based on the average value of all samples analyzed according to the sampling plans. The sample unit shall be the entire contents of the container.

(p) The sampling and acceptance procedure means the following:

(1) *Definitions*—(i) *Lot.* A collection of primary containers or units of the same size, type, and style manufactured or packed under similar conditions and handled as a single unit of trade.

(ii) *Lot size.* The number of primary containers or units in the lot.

(iii) *Sample size.* The total number of sample units drawn for examination from a lot.

(iv) *Sample unit.* A container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for the examination or testing as a single unit.

(v) *Defective.* Any sample unit shall be regarded as defective when the sample unit does not meet the criteria set forth in the standards.

(vi) *Acceptance number (c).* The maximum number of defective sample units permitted in the sample in order to consider the lot as meeting the specified requirements.

(vii) *Acceptable quality level (AQL).* The maximum percent of defective sample units permitted in a lot that will be accepted approximately 95 percent of the time.

(2) *Sampling plans:*

Lot size (primary containers)	Size of container	
	Net weight equal to or less than 1 kg (2.2 lb)	
	n	c
4,800 or less	13	2
4,801 to 24,000	21	3
24,001 to 48,000	29	4
48,001 to 84,000	48	6
84,001 to 144,000	84	9
144,001 to 240,000	126	13
Over 240,000	200	19
	Net weight greater than 1 kg (2.2 lb) but not more than 4.5 kg (10 lb)	
	n	c
2,400 or less	13	2
2,401 to 15,000	21	3
15,001 to 24,000	29	4
24,001 to 42,000	48	6
42,001 to 72,000	84	9
72,001 to 120,000	126	13
Over 120,000	200	19
	Net weight greater than 4.5 kg (10 lb)	
	n	c
600 or less	13	2
601 to 2,000	21	3
2,001 to 7,200	29	4
7,201 to 15,000	48	6
15,001 to 24,000	84	9
24,001 to 42,000	126	13
Over 42,000	200	19

n=number of primary containers in sample.
c=acceptance number.

Subpart B—Requirements for Specific Standardized Canned Fruits

§ 145.110 Canned applesauce.

(a) *Identity*—(1) *Definition.* Canned applesauce is the food prepared from comminuted or chopped apples (*Malus domestica* Borkhausen), which may or may not be peeled and cored, and which may have added thereto one or more of the optional ingredients specified in paragraph (a)(2) of this section. The apple ingredient is heated and, in accordance with good manufacturing practices, bruised apple particles, peel, seed, core material, carpel tissue, and other coarse, hard, or extraneous materials are removed. The food is sealed in containers. It is so processd by heat, either before or after sealing, as to prevent spoilage. The soluble solids content, measured by refractometer and expressed as percent sucrose (degrees Brix) with correction for temperature to the equivalent at 20° C (68° F), is not less than 9 percent (exclusive of the solids of any added optional nutritive carbohydrate sweeteners) as determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Edition, 1970, page 371, § 22.019, "Soluble Solids (By Refractometer) in Fresh and Canned Fruits, Jams, Marmalades, and Preserves—Official First Action"* without correction for water-insoluble solids, invert sugar, or other substances.

(2) *Optional ingredients.* The following safe and suitable optional ingredients may be used:

(i) Water.

(ii) Apple juice.

(iii) Salt.

(iv) Any organic acid added for the purpose of acidification. (Organic acids generally recognized as having a preservative effect are not permitted in applesauce except as provided for in paragraph (a)(2)(viii) of this section.)

(v) Nutritive carbohydrate sweeteners.

(vi) Spices.

(vii) Natural and artificial flavoring.

(viii) Either of the following:

(*a*) Erythorbic acid or ascorbic acid as an antioxidant preservative in an amount not to exceed 150 parts per million; or

(*b*) Ascorbic acid (vitamin C) in a quantity such that the total vitamin C in each 113 g (4 ounces) by weight of the finished food amounts to 60 mg. This requirement will be deemed to have been met if a reasonable overage of the vitamin, within limits of good manufacturing practice, is present to insure that the required level is maintained throughout the expected shelf life of the food under customary conditions of distribution.

(ix) Color additives in such quantity as to distinctly characterize the food unless such addition conceals damage or inferiority or makes the finished food appear better or of greater value than it is.

(3) *Nomenclature.* The name of the food is "applesauce". The name of the food shall include a declaration indicating the presence of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice that characterizes the product. If a nutritive sweetener as provided for in paragraph (a)(2)(v) of this section is added and the soluble solids content of the finished food is not less than 16.5 percent as determined by the method referred to in paragraph (a)(1) of this section, the name may include the word "sweetened". If no such sweetener is added, the name may include the word "unsweetened."

(4) *Label declaration.* Each of the optional ingredients shall be declared on the label as required by the applicable sections of Part 101 of this chapter. However, when ascorbic acid (vitamin C) is added as provided for in paragraph (a)(2)(viii)(*b*) of this section, after the application of heat to the apples, preservative labeling requirements do not apply.

(b) [Reserved]

(c) *Fill of container*—(1) The standard of fill of container for canned applesauce is a fill of not less than 90 percent of the total capacity of the container, as determined by the general method for fill of containers prescribed in § 130.12 (b) of this chapter; except that in the case of glass containers having a total capacity of 192 ml (6½ fluid ounces) or less, the fill is not less than 85 percent.

(2) Sampling and acceptance procedure: A lot will be deemed to fall below

*Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

the standard of fill when the number of "defectives" exceeds the acceptance number "c" in the sampling plans prescribed in paragraph (c)(2)(ii) of this section.

(i) Definitions of terms to be used in the sampling plans in paragraph (c)(2)(ii) of this section are as follows:

(*a*) *Lot.* A collection of primary containers or units of the same size, type, and style manufactured or packed under similar conditions and handled as a single unit of trade.

(*b*) *Lot size.* The number of primary containers or units in the lot.

(*c*) *Sample size "n."* The total number of sample units drawn for examination from a lot as indicated in paragraph (c)(2)(ii) of this section.

(*d*) *Sample unit.* A container, the entire contents of a container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for examination or testing as a single unit.

(*e*) *Defective.* A container that falls below the requirement for minimum fill prescribed in paragraph (c)(1) of this section is considered a "defective."

(*f*) *Acceptable number "c."* The maximum number of defective sample units permitted in the sample in order to consider the lot as meeting the specified requirements.

(*g*) *Acceptable quality level (AQL).* The maximum percent of defective sample units permitted in a lot that will be accepted approximately 95 percent of the time.

(ii) Sampling and acceptance:

Acceptable quality level (AQL) 6.5

Lot size (primary containers)	Size of container	
	Net weight equal to or less than 1 kg (2.2 lb)	
	n	c
4,800 or less	13	2
4,801 to 24,000	21	3
24,001 to 48,000	29	4
48,001 to 84,000	48	6
84,001 to 144,000	84	9
144,001 to 240,000	126	13
Over 240,000	200	19
	Net weight greater than 1 kg (2.2 lb) but not more than 4.5 kg (10 lb)	
	n	c
2,400 or less	13	2
2,401 to 15,000	21	3
15,001 to 24,000	29	4
24,001 to 42,000	48	6
42,001 to 72,000	84	9
72,001 to 120,000	126	13
Over 120,000	200	19
	Net weight greater than 4.5 kg (10 lb)	
	n	c
600 or less	13	2
601 to 2,000	21	3
2,001 to 7,200	29	4
7,201 to 15,000	48	6
15,001 to 24,000	84	9
24,001 to 42,000	126	13
Over 42,000	200	19

n=number of primary containers in sample.
c=acceptance number.

(3) If canned applesauce falls below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

§ 145.115 Canned apricots.

(a) *Identity*—(1) *Ingredients.* Canned apricots is the food prepared from mature apricots of one of the optional styles specified in paragraph (a)(2) of this section, which may be packed as solid pack or in one of the optional packing media specified in paragraph (a)(3) of this section. Such food may also contain one, or any combination of two or more of the following safe and suitable optional ingredients:

(i) Natural and artificial flavors.

(ii) Spice.

(iii) Vinegar, lemon juice, or organic acids.

(iv) Apricot pits, except in the cases of unpeeled whole apricots and peeled whole apricots, in a quantity not more than 1 apricot pit to each 227 grams (8 ounces) of finished canned apricots.

(v) Apricot kernels, except in the cases of unpeeled whole apricots and peeled whole apricots, and except when optional ingredient under paragraph (a)(4) of this section is used.

(vi) Ascorbic acid in an amount no greater than necessary to preserve color.

Such food is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

(2) *Optional styles of the apricot ingredient.* The optional styles of the apricot ingredient referred to in paragraph (a) of this section are peeled or unpeeled:

(i) Whole.

(ii) Halves.

(iii) Quarters.

(iv) Slices.

(v) Pieces or irregular pieces.

Each such ingredient, except in the cases of unpeeled whole apricots and peeled whole apricots, is pitted.

(3) *Packing media.* (i) The optional packing media referred to in paragraph (a)(1) of this section, as defined in § 145.3 are:

(*a*) Water.

(*b*) Fruit juice(s) and water.

(*c*) Fruit juice(s).

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in § 145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in Part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in § 145.3.

(ii) When a sweetener is added as a part of any such liquid packing medium, the density range of the resulting packing medium expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure prescribed in § 145.3(m) shall be designated by the appropriate name for the respective density ranges, namely:

(*a*) When the density of the solution is 10 percent or more but less than 16 percent, the medium shall be designated as "slightly sweetened water"; or "extra light sirup"; "slightly sweetened fruit juice(s) and water"; or "slightly sweetened fruit juice(s)", as the case may be.

(*b*) When the density of the solution is 16 percent or more but less than 21 percent, the medium shall be designated as "light sirup"; "lightly sweetened fruit juice(s) and water"; or "lightly sweetened fruit juice(s)", as the case may be.

(*c*) When the density of the solution is 21 percent or more but less than 25 percent, the medium shall be designated as "heavy sirup"; "heavily sweetened fruit juice(s) and water"; or "heavily sweetened fruit juice(s)", as the case may be.

(*d*) When the density of the solution is 25 percent or more but not more than 40 percent, the medium shall be designated as "extra heavy sirup"; "extra heavily sweetened fruit juice(s) and water"; or "extra heavily sweetened fruit juice(s)", as the case may be.

(4) *Labeling requirements.* (i) The name of the food is "apricots". The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, "Spice Added", or in lieu of the word "Spice", the common name of the spice, "Seasoned with Vinegar" or "Seasoned with Apricot Kernels". When two or more of the optional ingredients specified in paragraph (a)(1)(ii) through (iv), inclusive, of this section are used, such words may be combined as for example, "Seasoned with Cider Vinegar, Cloves, Cinnamon Oil and Apricot Kernels".

(ii) The style of the apricot ingredient as provided in paragraph (a)(2) of this section and the name of the packing medium as used in paragraph (a)(3)(i) and (ii) of this section, preceded by "In" or "Packed in" or the words "solid pack", where applicable, shall be included as part of the name or in close proximity to the name of the food, except that pieces or irregular pieces shall be designated "Pieces", "Irregular pieces", or "Mixed pieces of irregular sizes and shapes". The style of the apricot ingredient shall be preceded or followed by "Unpeeled" or "Peeled", as the case may be. "Halves" may be alternatively designated "Halved", "Quarters" as "Quartered" and "Slices" as "Sliced". When the packing medium is prepared with a sweetener(s) which imparts a taste, flavor or other characteristic to the finished food in addition to sweetness, the name of the packing medium shall be accompanied by the name of such sweetener(s), as for example in the case of a mixture of brown

sugar and honey, an appropriate statement would be "_____ sirup of brown sugar and honey" the blank to be filled in with the word "light", "heavy", or "extra heavy" as the case may be. When the liquid portion of the packing media provided for in paragraph (a)(3)(i) and (ii) of this section consists of fruit juice(s), such juice(s) shall be designated in the name of the packing medium as:

(a) In the case of a single fruit juice, the name of the juice shall be used in lieu of the word "fruit".

(b) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word "fruit" in the name of the packing medium, or be declared on the label as specified in paragraph (a)(4)(iii) of this section, and

(c) In the case of a single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words "from concentrate(s)" shall follow the word "juice(s)" in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (a)(4)(iii) of this section.

(iii) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (a)(4)(ii)(b) of this section, such names and the words "from concentrate," as specified in paragraph (a)(4)(ii)(c) of this section, shall appear in an ingredient statement pursuant to the requirements of § 101.3(d) of this chapter.

(iv) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(b) *Quality*—(1) The standard of quality for canned apricots is as follows:

(i) All units tested in accordance with the method prescribed in paragraph (b)(2) of this section are pierced by a weight of not more than 300 grams.

(ii) In the cases of whole apricots, halves, and quarters, the weight of the largest unit in the container is not more than twice the weight of the smallest unit therein.

(iii) Not more than 20 percent of the units in the container are blemished with scab, hail injury, discoloration, or other abnormalities.

(iv) In the cases of whole apricots, halves, and quarters, all units are untrimmed, or are so trimmed as to preserve normal shape.

(v) Except in the case of mixed pieces of irregular sizes and shapes, not more than 5 percent of the units in a container of 20 or more units, and not more than 1 unit in a container of less than 20 units, are crushed or broken. (A unit which has lost its normal shape because of ripeness and which bears no mark of crushing shall not be considered to be crushed or broken.)

(2) Canned apricots shall be tested by the following method to determine whether or not they meet the requirements of paragraph (b)(1)(i) of this section: So trim a test piece from the unit as to fit, with peel surface up, into a supporting receptacle. If the unit is of different firmness in different parts of its peel surface, trim the piece from the firmest part. If the piece is unpeeled, remove the peel. The top of the receptacle is circular in shape, of 1⅛ inches inside diameter, with vertical sides; or rectangular in shape, ¾ inch by 1 inch inside measurements, with ends vertical and sides sloping downward and joining at the center at a vertical depth of ¾ inch. Use the circular receptacle for testing units of such size that a test piece can be trimmed therefrom to fit it. Use the rectangular receptacle for testing other units. Test no unit from which a test piece with rectangular peel surface at least ½ inch by 1 inch cannot be trimmed. Test the piece by means of a round metal rod 7/16 inch in diameter. To the upper end of the rod is affixed a device to which weight can be added. The rod is held vertically by a support through which it can freely move upward or downward. The lower end of the rod is a plane surface to which the vertical axis of the rod is perpendicular. Adjust the combined weight of the rod and device to 100 grams. Set the receptacle so that the surface of the test piece is held horizontally. Lower the end of the rod to the approximate center of such surface, and add weight to the device at a uniform, continuous rate of 12 grams per second until the rod pierces the test piece. Weigh the rod and weighted device. Test all units in containers of 50 units or less, except those units too small for testing or too soft for trimming. Test at least 50 units, taken at random, in containers of more than 50 units; but if less than 50 units are of sufficient size and firmness for testing, test those which are of sufficient size and firmness.

(3) If the quality of canned apricots falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in § 130.14(a) of this chapter, in the manner and form therein specified; but in lieu of such general statement of substandard quality, the label may bear the alternative statement "Below standard in quality _____", the blank to be filled in with the words specified after the corresponding number of each subparagraph of paragraph (b)(1) of this section which such canned apricots fail to meet, as follows: (i) "Not tender"; (ii) "Mixed sizes"; (iii) "Blemished"; (iv) "Unevenly trimmed"; (v) "Partly crushed or broken". Such alternative statement shall immediately and conspicuously precede or follow, without intervening written, printed, or graphic matter, the name "apricots" and any words and statements required or authorized to appear with such name by § 145.115(a)(2).

(c) *Fill of container*—(1) The standard of fill of container for canned apricots is the maximum quantity of the optional apricot ingredient that can be sealed in the container and processed by heat to prevent spoilage, without crushing or breaking such ingredient.

(2) If canned apricots fall below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

§ 145.116 Artificially sweetened canned apricots.

(a) Artificially sweetened canned apricots is the food which conforms to the definition and standard of identity prescribed for canned apricots by § 145.115(a), except that in lieu of a packing medium specified in § 145.115(a)(3), the packing medium used is water artificially sweetened with saccharin, sodium saccharin, or a combination of both. Such packing medium may be thickened with pectin and may contain any mixture of any edible organic salt or salts and any edible organic acid or acids as a flavor-enhancing agent, in a quantity not more than is reasonably required for that purpose.

(b)(1) The specified name of the food is "artifically sweetened _____", the blank being filled in with the name prescribed by § 145.115(a) for canned apricots having the same optional apricot ingredient.

(2) The artificially sweetened food is subject to the requirements for label statement of optional ingredients used, as prescribed for canned apricots by § 145.115(a). If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin". When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

§ 145.118 Canned apricots with rum.

Canned apricots with rum conforms to the definition and standard of identity and is subject to the requirements for label statement of optional ingredients, prescribed for canned apricots by § 145.115(a), except that it contains added rum in such amount that its alcohol content is more than 3 percent but less than 5 percent by weight.

§ 145.120 Canned berries.

(a) *Ingredients.* Canned berries is the food prepared from any suitable variety of one of the optional berry ingredients specified in paragraph (b) of this section, which may be packed in one of the optional packing media specified in paragraph (c) of this section. It may contain safe and suitable natural and artificial flavors. It is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

(b) *Varietal types.* The optional berry ingredients referred to in paragraph (a) of this section are prepared from stemmed fruit of the following optional varietal types of berry ingredient; namely:

(1) Raspberry varieties conforming to the characteristics of *Rubus idaeus* L. or *Rubus occidentalis* L.

(2) Blackberries.
(3) Blueberries.
(4) Boysenberries.
(5) Dewberries.
(6) Gooseberries.
(7) Huckleberries.
(8) Loganberries.
(9) Strawberries.
(10) Youngberries.

(c) *Packing media.* (1) The optional packing media referred to in paragraph (a) of this section, as defined in § 145.3 are:

(i) Water.
(ii) Fruit juice(s) and water.
(iii) Fruit juice(s).

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in § 145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in Part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in § 145.3.

(2) When a sweetener is added as a part of any such liquid packing medium, the four density ranges of the resulting packing media hereinafter specified for each berry ingredient, expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure described in § 145.3(m), shall be designated by the appropriate name for each of the respective density ranges for each berry ingredient as:

(i) "Slightly sweetened water"; or "extra light sirup"; "slightly sweetened fruit juice(s) and water"; or "slightly sweetened fruit juice(s)", as the case may be.

(ii) "Light sirup", when the liquid used is water; "lightly sweetened fruit juice(s) and water"; or "lightly sweetened fruit juice(s)", as the case may be.

(iii) "Heavy sirup", when the liquid used is water; or "heavily sweetened fruit juice(s) and water"; or "heavily sweetened fruit juice(s)", as the case may be.

(iv) "Extra heavy sirup", when the liquid used is water; or "extra heavily sweetened fruit juice(s) and water"; or "extra heavily sweetened fruit juice(s)", as the case may be.

The density ranges referred to herein are:

Optional berry ingredient	Density ranges							
	(i)		(ii)		(iii)		(iv)	
	Minimum	Maximum less than	Minimum	Maximum less than	Minimum	Maximum less than	Minimum	Maximum not more than
Raspberries	11	15	15	20	20	27	27	35
Blackberries		14	14	19	19	24	24	35
Blueberries		15	15	20	20	25	25	35
Boysenberries		14	14	19	19	24	24	35
Dewberries		14	14	19	19	24	24	35
Gooseberries		14	14	20	20	26	26	35
Huckleberries		15	15	20	20	25	25	35
Loganberries		14	14	19	19	24	24	35
Strawberries		14	14	19	19	27	27	35
Youngberries		14	14	19	19	24	24	35

(d) *Labeling requirements.* (1) The name of the food is the appropriate name of the berry ingredient specified in paragraph (b) of this section.

(2) The name of the packing medium, as used in paragraph (c)(1) of this section preceded by "In" or "Packed in" as provided in paragraph (c) of this section and, in the case of raspberries other than red raspberries provided for in paragraph (b) of this section, the name of such packing medium and the color of such raspberry shall be included as part of the name or in close proximity to the name of the food. When the packing medium is prepared with a sweetener(s) which imparts a taste, flavor or other characteristic to the finished food in addition to sweetness, the name of the packing medium shall be accompanied by the name of such sweetener(s), as for example in the case of a mixture of brown sugar and honey, an appropriate statement would be "_____ sirup of brown sugar and honey" the blank to be filled in with the word "light", "heavy", or "extra heavy" as the case may be. When the liquid portion of the packing media provided for in paragraph (c)(1) and (2) of this section consists of fruit juice(s), such juice(s) shall be designated in the name of the packing medium as:

(i) In the case of a single fruit juice, the name of the juice shall be used in lieu of the word "fruit";

(ii) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word "fruit" in the name of the packing medium, or be declared on the label as specified in paragraph (c) of this section; and

(iii) In the case of a single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words "from concentrate(s)" shall follow the word "juice(s)" in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (d)(3) of this section.

(3) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (d)(2)(ii) of this section, such names and the words "from concentrate", as specified in paragraph (d)(2)(iii) of this section, shall appear in an ingredient statement pursuant to the requirements of § 101.3(d) of this chapter.

(4) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 145.125 Canned cherries.

(a) *Identity*—(1) *Ingredients.* Canned cherries is the food prepared from one of the optional fresh or previously canned cherry ingredients specified in paragraph (a)(2) of this section, which may be packed in one of the optional packing media specified in paragraph (a)(3) of this section. Such food may also contain one, or any combination of two or more, of the following safe and suitable optional ingredients:

(i) Natural and artificial flavors.
(ii) Spice.
(iii) Vinegar, lemon juice, or organic acids.

Such food is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

(2) *Varietal types and styles.* The optional cherry ingredients referred to in paragraph (a)(1) of this section are prepared from mature pitted or unpitted cherries of the red tart or alternatively, red sour, light sweet or dark sweet varietal group.

(3) *Packing media.* (i) The optional packing media referred to in paragraph (a)(1) of this section, as defined in § 145.3 are:

(a) Water.
(b) Fruit juice(s) and water.
(c) Fruit juice(s).

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in § 145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in Part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in § 145.3.

(ii) When a sweetener is added as a part of any such liquid packing medium, the density range of the resulting packing medium expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure prescribed in § 145.3(m) shall be designated by the appropriate name for the respective density ranges, namely:

(a) In the case of sweet cherries:

(*i*) When the density of the solution is less than 16 percent, the medium shall be designated as "slightly sweetened water"; or "extra light sirup"; "slightly sweetened fruit juice(s) and water"; or "slightly sweetened fruit juice(s)", as the case may be.

(*ii*) When the density of the solution is 16 percent or more but less than 20 percent, the medium shall be designated as "light sirup"; "lightly sweetened fruit juice(s) and water"; or "lightly sweetened fruit juice(s)", as the case may be.

(iii) When the density of the solution is 20 percent or more but less than 25 percent, the medium shall be designated as "heavy sirup"; "heavily sweetened fruit juice(s) and water"; or "heavily sweetened fruit juice(s)", as the case may be.

(iv) When the density of the solution is 25 percent or more but not more than 35 percent, the medium shall be designated as "extra heavy sirup"; "extra heavily sweetened fruit juice(s) and water"; or "extra heavily sweetened fruit juice(s)", as the case may be.

(b) In the case of red tart cherries:

(i) When the density of the solution is less than 18 percent, the medium shall be designated as "slightly sweetened water"; "slightly sweetened fruit juice(s) and water"; or "slightly sweetened fruit juice(s)", as the case may be.

(ii) When the density of the solution is 18 percent or more but less than 22 percent, the medium shall be designated as "light sirup"; "lightly sweetened fruit juice(s) and water"; or "lightly sweetened fruit juice(s)", as the case may be.

(iii) When the density of the solution is 22 percent or more but less than 28 percent, the medium shall be designated as "heavy sirup"; "heavily sweetened fruit juice(s) and water"; or "heavily sweetened fruit juice(s)", as the case may be.

(iv) When the density of the solution is 28 percent or more but not more than 45 percent, the medium shall be designated as "extra heavy sirup"; "extra heavily sweetened fruit juice(s) and water"; or "extra heavily sweetened fruit juice(s)", as the case may be.

(4) *Labeling requirements.* (i) The name of the food is "cherries". The optional varietal type as set forth in paragraph (a)(2) of this section, preceded or followed by the word "pitted" when this is the fact, shall be a part of the name. The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, "Spice added", or in lieu of the word "Spice", the common name of the spice, or "Seasoned with lemon juice". When two or more of the optional ingredients specified in paragraph (a)(1)(ii) and (iii) of this section are used, such words may be combined as for example, "Seasoned with cider vinegar, cloves, and cinnamon oil".

(ii) The color type and style of the cherry ingredient as provided in paragraph (a)(2) of this section and the name of the packing medium specified in paragraph (a)(3)(i) and (ii) of this section, preceded by "In" or "Packed in" or the words "solid pack", where applicable, shall be included as part of the name or in close proximity to the name of the food. When the packing medium is prepared with a sweetener(s) which imparts a taste, flavor or other characteristic to the finished food in addition to sweetness, the name of the packing medium shall be accompanied by the name of such sweetener(s), as for example in the case of a mixture of brown sugar and honey, an appropriate statement would be "_____ sirup of brown sugar and honey" the blank to be filled in with the word "light", "heavy", or "extra heavy" as the case may be. When the liquid portion of the packing media provided for in paragraph (a)(3)(i) and (ii) of this section consists of fruit juice(s), such juice(s) shall be designated in the name of the packing medium as:

(a) In the case of a single fruit juice, the name of the juice shall be used in lieu of the word "fruit";

(b) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word "fruit" in the name of the packing medium, or be declared on the label as specified in paragraph (a)(4)(iii) of this section; and

(c) In the case of a single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words "from concentrate(s)" shall follow the word "juice(s)" in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (a)(4)(iii) of this section.

(iii) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (a)(4)(ii)(b) of this section, such names and the words "from concentrate", as specified in paragraph (a)(4)(ii)(c) of this section, shall appear in an ingredient statement pursuant to the requirements of § 101.3(d) of this chapter.

(iv) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(b) Quality—(1) The standard of quality for canned cherries is as follows:

(i) In the case of pitted cherries, not more than 1 pit is present in each 20 ounces of canned cherries, as determined by the method prescribed in paragraph (b)(2)(i) of this section.

(ii) In the case of unpitted cherries, the weight of each cherry in the container is not less than 1/10 ounce.

(iii) In the case of unpitted cherries, the weight of the largest cherry in the container is not more than twice the weight of the smallest cherry therein.

(iv) In the case of unpitted cherries, the total weight of pits is not more than 12 percent of the weight of drained cherries, as determined by the method prescribed in paragraph (b)(2)(ii) of this section.

(v) Not more than 15 percent by count of the cherries in the container are blemished with scab, hail injury, discoloration, scar tissue or other abnormality. A cherry showing skin discoloration (other than scald) having an aggregate area exceeding that of a circle 9/32 inch in diameter is considered to be blemished. A cherry showing discoloration of any area but extending into the fruit tissue is also considered to be blemished.

(2)(i) Pitted canned cherries shall be tested by the following method to determine whether or not they comply with the requirements of paragraph (b)(1)(i) of this section: Take at random such number of containers as to have a total quantity of contents of at least 24 pounds. Open the containers and weigh the contents. Count the pits and pieces of pit shell in such total quantity. Count a piece of pit shell equal to or smaller than one-half pit shell as one-half pit, and a piece of pit shell larger than one-half pit shell as one pit; but when two or more pieces of pit shell are within or attached to a single cherry, count such pieces as one-half pit if their combined size is equivalent to that of one-half pit shell or less, and as one pit if their combined size is equivalent to that of more than one-half pit shell. From the total number of pits so counted and the combined weight of the contents of all the containers, calculate the number of pits present in each 20 ounces of canned cherries.

(ii) Unpitted canned cherries shall be tested by the following method to determine whether or not they comply with the requirements of paragraph (b)(1)(iv) of this section: Tilt the opened container so as to distribute the contents over the meshes of a circular sieve which has previously been weighed. The diameter of the sieve is 8 inches if the quantity of the contents of the container is less than 3 pounds, or 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is No. 8 woven-wire cloth which complies with the specifications for such cloth set forth on page 3 of "Standard Specifications for Sieves," published October 25, 1938, by United States Department of Commerce, National Bureau of Standards. Without shifting the cherries, so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and drained cherries. The weight so found, less the weight of the sieve, shall be considered to be the weight of drained cherries. Pit the cherries and wash the pits free from adhering flesh. Drain and weigh the pits by the method prescribed above. Divide the weight of pits so found by the weight of drained cherries, and multiply by 100.

(3) If the quality of canned cherries falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in § 130.14(a) of this chapter, in the manner and form therein specified; but in lieu of such general statement of substandard quality, the label may bear the alternative statement "Below Standard in Quality _____", the blank to be filled in with the words specified after the corresponding number of each subparagraph of paragraph (b)(1) of this section which such canned cherries fail to meet, as follows: (i) "Partially pitted"; (ii) "Small"; (iii) "Mixed sizes"; (iv) "Thin-fleshed"; (v) "Blemished". Such alternative statement shall immediately and conspicuously precede or follow, without intervening written, printed, or graphic matter, the name "Cherries" and

any words and statements required or authorized to appear with such name by § 145.125(a)(2).

(c) *Fill of container*—(1) The standard of fill of container for canned cherries is the maximum quantity of the optional cherry ingredient that can be sealed in the container and processed by heat to prevent spoilage, without crushing such ingredient.

(2) If canned cherries fall below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

§ 145.126 Artificially sweetened canned cherries.

(a) Artificially sweetened canned cherries is the food which conforms to the definition and standard of identity prescribed for canned cherries by § 145.125(a), except that in lieu of a packing medium specified in § 145.125(a)(3), the packing medium used is water artificially sweetened with saccharin, sodium saccharin, or a combination of both. Such packing medium may be thickened with pectin and may contain any mixture of any edible organic salt or salts and any edible organic acid or acids as a flavor-enhancing agent, in a quantity not more than is reasonably required for that purpose.

(b)(1) The specified name of the food is "artificially sweetened _____", the blank being filled in with the name prescribed by § 145.125(a) for canned cherries having the same optional cherry ingredient.

(2) The artificially sweetened food is subject to the requirements for label statement of optional ingredients used, as prescribed for canned cherries by § 145.125(a). If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin". When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

§ 145.128 Canned cherries with rum.

Canned cherries with rum conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for canned cherries by § 145.125(a), except that it contains added rum in such amount that its alcohol content is more than 3 percent but less than 5 percent by weight.

§ 145.130 Canned figs.

(a) *Ingredients.* Canned figs is the food prepared from one of the optional fig ingredients specified in paragraph (b) of this section and one of the optional packing media specified in paragraph (c) of this section, to which lemon juice, concentrated lemon juice or organic acid(s) is added, when necessary to reduce the pH of the finished product to pH 4.9 or below. Such food may also contain one, or any combination of two or more of the following safe and suitable optional ingredients:

(1) Natural and artificial flavoring.
(2) Spice.
(3) Vinegar.
(4) Unpeeled segments of citrus fruits.
(5) Salt.

Such food is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

(b) *Varietal types.* The optional fig ingredients referred to in paragraph (a) of this section are prepared from mature figs of the light or dark varieties. Figs (or whole figs), split figs (or broken figs), or any combination thereof are optional fig ingredients. A "whole fig" is one which is whole, but may be slightly cracked, provided it retains its natural conformation without exposing the interior. A "split" or "broken" fig is one that is open to such an extent that the seed cavity is exposed. The shape of the fruit may be distorted, and the fruit may or may not be broken apart into entirely separate pieces.

(c) *Packing media.* (1) The optional packing media referred to in paragraph (a) of this section, as defined in § 145.3 are:

(i) Water.
(ii) Fruit juice(s) and water.
(iii) Fruit juice(s).

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in § 145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in Part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in § 145.3.

(2) When a sweetener is added as a part of any such liquid packing medium, the density range of the resulting packing medium expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure prescribed in § 145.3(m) shall be designated by the appropriate name for the respective density ranges, namely:

(i) When the density of the solution is 11 percent or more but less than 16 percent, the medium shall be designated as "slightly sweetened water"; or "extra light syrup"; "slightly sweetened fruit juice(s) and water"; or "slightly sweetened fruit juice(s)", as the case may be.

(ii) When the density of the solution is 16 percent or more but less than 21 percent, the medium shall be designated as "light sirup"; "lightly sweetened fruit juice(s) and water"; or "lightly sweetened fruit juice(s)", as the case may be.

(iii) When the density of the solution is 21 percent or more but less than 26 percent, the medium shall be designated as "heavy sirup"; "heavily sweetened fruit juice(s) and water"; or "heavily sweetened fruit juice(s)", as the case may be.

(iv) When the density of the solution is 26 percent or more but not more than 35 percent, the medium shall be designated as "extra heavy sirup"; "extra heavily sweetened fruit juice(s) and water"; or "extra heavily sweetened fruit juice(s)", as the case may be.

(d) *Labeling requirements.* (1) The name of the food is "figs". The words "broken" or "split" shall be a part of the name when the optional fig ingredient is a broken or split fig. The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, "Spice added", or in lieu of the word "Spice", the common name of the spice, "Seasoned with vinegar" or "Seasoned with unpeeled segments of citrus fruits". When two or more of the optional ingredients specified in paragraph (a)(2) through (5), inclusive, of this section are used, such words may be combined as for example, "Seasoned with cider vinegar, cloves, cinnamon oil and unpeeled segments of citrus fruits."

(2) The name of the packing medium as used in paragraph (c)(1) of this section, preceded by "In" or "Packed in", as provided in paragraph (c) of this section, shall be included as part of the name or in close proximity to the name of the food. When the packing medium is prepared with a sweetener(s) which imparts a taste, flavor or other characteristic to the finished food other than sweetness, as for example, a mixture of brown sugar and honey, the statement "_____ sirup of brown sugar and honey" the blank to be filled in with the word "light", "heavy", or "extra heavy", as the case may be, shall be included as part of the name or in close proximity to the name of the food. When the liquid portion of the packing media provided for in paragraph (c)(1) and (2) of this section consists of fruit juice(s), such juice(s) shall be designated in the name of the packing medium as:

(i) In the case of a single fruit juice, the name of the juice shall be used in lieu of the word "fruit";

(ii) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word "fruit" in the name of the packing medium, or be declared on the label as specified in paragraph (d)(3) of this section; and

(iii) In the case of a single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words "from concentrate(s)" shall follow the word "juice(s)" in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (d)(3) of this section.

(3) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (d)(2)(ii) of this section, such names and the words "from contrate", as specified in paragraph (d)(2)(iii) of this section, shall appear in an ingredient statement pursuant to the requirements of § 101.3(d) of this chapter.

(4) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 145.131 Artificially sweetened canned figs.

(a) Artificially sweetened canned figs is the food which conforms to the definition and standard of identity prescribed for canned figs by § 145.130, except that in lieu of a packing medium specified in § 145.130(c), the packing medium used is water artificially sweetened with saccharin, sodium saccharin, or a combination of both. Such packing medium may be thickened with pectin and may contain any mixture of any edible organic salt or salts and any edible organic acid or acids as a flavor-enhancing agent, in a quantity not more than is reasonably required for that purpose.

(b) (1) The specified name of the food is "artificially sweetened _____", the blank being filled in with the name prescribed by § 145.130 for canned figs having the same optional fig ingredient.

(2) The artificially sweetened food is subject to the requirements for label statement of optional ingredients used, as prescribed for canned figs by § 145.130. If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin". When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

§ 145.134 Canned preserved figs.

(a) Canned preserved figs is the food prepared from one of the optional fig ingredients specified in paragraph (b) of this section and the packing medium specified in paragraph (c) of this section, to which citric acid or lemon juice or concentrated lemon juice is added, if necessary, in such quantity as to reduce the pH of the finished product to 4.9 or below. The figs are precooked in the packing medium, sealed in a container, and so processed by heat, either before or after sealing, as to prevent spoilage.

(b) The optional fig ingredients referred to in paragraph (a) of this section are whole mature figs of the light or dark varieties that may be either peeled or unpeeled.

(c) (1) The packing medium referred to in paragraph (a) of this section is prepared from water and one of the following optional sweetening ingredients:

(i) Sugar.

(ii) Invert sugar sirup.

(iii) Any mixture of optional sweetening ingredients designated in paragraph (c) (1) (i) and (ii) of this section.

(iv) Any of the optional sweetening ingredients designated in paragraph (c) (1) (i), (ii), and (iii) of this section with dextrose: *Provided*, That the weight of the solids of dextrose does not exceed one-third of the total weight of the solids of the combined sweetening ingredients.

(v) Any of the optional sweetening ingredients designated in paragraph (c) (1) (i), (ii), and (iii) of this section with corn sirup or with dried corn sirup or with glucose sirup or with dried glucose sirup, or with any two or more of these: *Provided*, That the weight of the solids of corn sirup, dried corn sirup, glucose sirup, dried glucose sirup or the sum of the weights of the solids of corn sirup, dried corn sirup, glucose sirup, and dried glucose sirup, in case two or more of these are used, does not exceed one-fourth of the total weight of the solids of the combined sweetening ingredients.

(vi) Any mixture of the optional ingredients designated in paragraph (c) (1) (iv) and (v) of this section.

(2) The density of the packing medium described in paragraph (c) (1) of this section, as measured on the Brix hydrometer 15 days or more after the figs are canned, is not less than 50° and not more than 55°.

(d) (1) The name of the food is "Preserved Figs—Precooked in Sirup". For the purpose of label declaration, the words "Precooked in Sirup" may appear immediately below the words "Preserved Figs", but there shall be no intervening written, printed, or graphic matter, and the letters used for the words "Precooked in Sirup" shall be of the same type style and not less than one-half the height of the letters in the words "Preserved Figs".

(2) The label shall indicate which optional fig ingredient specified in paragraph (b) of this section is used.

(e) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words herein specified, showing the optional fig ingredient used, shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter, except that the varietal name of the figs may so intervene.

§ 145.135 Canned fruit cocktail.

(a) *Identity*—(1) *Ingredients.* Canned fruit cocktail, canned cocktail fruits, canned fruits for cocktail, is the food prepared from the mixture of fresh, frozen, or previously canned fruit ingredients of mature fruits in the forms and proportions as provided in paragraph (a) (2) of this section, and one of the optional packing media specified in paragraph (a) (3) of this section. Such food may also contain one, or any combination of two or more, of the following safe and suitable optional ingredients:

(i) Natural and artificial flavors.

(ii) Spice.

(iii) Vinegar, lemon juice, or organic acids.

(iv) Ascorbic acid in an amount no greater than necessary to preserve color. Such food is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

(2) *Varietal types and styles.* The fruit ingredients referred to in paragraph (a) (1) of this section, the forms of each, and the percent by weight of each in the mixture of drained fruit from the finished canned fruit cocktail are as follows:

(i) *Peaches.* Any firm yellow variety of the species *Prunus persica* L., excluding nectarine varieties, which are pitted, peeled, and diced, not less than 30 percent and not more than 50 percent.

(ii) *Pears.* Any variety, of the species *Pyrus communis* L. or *Pyrus sinensis* L., which are peeled, cored, and diced, not less than 25 percent and not more than 45 percent.

(iii) *Pineapples.* Any variety, of the species *Ananas comosus* L., which are peeled, cored, and cut into sectors or into dice, not less than 6 percent and not more than 16 percent.

(iv) *Grapes.* Any seedless variety, of the species *Vitis vinifera* L., or *Vitis labrusca* L., not less than 6 percent and not more than 20 percent.

(v) *Cherries.* Approximate halves or whole pitted cherries of the species *Prunus cerasus* L., not less than 2 percent and not more than 6 percent, of the following types:

(a) Cherries of any light, sweet variety;

(b) Cherries artificially colored red; or

(c) Cherries artificially colored red and flavored, natural or artificial.

Provided, That each 127.5 grams (4½ ounces avoirdupois) of the finished canned fruit cocktail and each fraction thereof greater than 56.7 grams (2 ounces avoirdupois) contain not less than 2 sectors or 3 dice of pineapple and not less than 1 approximate half of the optional cherry ingredient.

(3) *Packing media.* (i) The optional packing media referred to in paragraph (a) (1) of this section, as defined in § 145.3 are:

(a) Water.

(b) Fruit juice(s) and water.

(c) Fruit juice(s).

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in § 145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in Part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in § 145.3.

(ii) When a sweetener is added as a part of any such liquid packing medium, the density range of the resulting packing medium expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure prescribed in § 145.3(m) shall be designated by the appropriate name for the respective density ranges, namely:

(a) When the density of the solution is 10 percent or more, but less than 14 percent, the medium shall be designated as "slightly sweetened water"; or "extra light sirup"; "slightly sweetened fruit juice(s) and water"; or "slightly sweetened fruit juice(s)", as the case may be.

(b) When the density of the solution is 14 percent or more but less than 18 percent, the medium shall be designated as "light sirup"; "lightly sweetened fruit juice(s) and water"; or "lightly sweetened fruit juice(s)", as the case may be.

(c) When the density of the solution is 18 percent or more but less than 22 percent, the medium shall be designated as "heavy sirup"; "heavily sweetened fruit juice(s) and water"; or "heavily sweetened fruit juice(s)", as the case may be.

(*d*) When the density of the solution is 22 percent or more but not more than 35 percent, the medium shall be designated as "extra heavy sirup"; "extra heavily sweetened fruit juice(s) and water"; or "extra heavily sweetened fruit juice(s)", as the case may be.

(4) *Labeling requirements.* (i) The name of the food is "fruit cocktail", "cocktail fruits", or "fruits for cocktail". The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, "Spice added", or in lieu of the word "Spice", the common name of the spice, "Seasoned with vinegar" or "Seasoned with lemon juice". When two or more of the optional ingredients specified in paragraph (a) (1) (ii) and (iii) of this section are used, such words may be combined as for example, "Seasoned with cider vinegar, cloves, cinnamon oil and lemon juice".

(ii) The name of the packing medium as used in paragraph (a) (3) (i) and (ii) of this section, preceded by "In" or "Packed in" shall be included as part of the name or in close proximity to the name of the food. When the packing medium is prepared with a sweetener(s) which imparts a taste, flavor or other characteristic to the finished food in addition to sweetness, the name of the packing medium shall be accompanied by the name of such sweetener(s), as for example, in the case of a mixture of brown sugar and honey, an appropriate statement would be "_____ sirup of brown sugar and honey" the blank to be filled in with the word "light", "heavy", or "extra heavy" as the case may be. When the liquid portion of the packing media provided for in paragraph (a) (3) (i) and (ii) of this section consists of fruit juice(s), such juice(s) shall be designated in the packing medium as:

(*a*) In the case of a single fruit juice, the name of the juice shall be used in lieu of the word "fruit";

(*b*) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word "fruit" in the name of the packing medium, or be declared on the label as specified in paragraph (a) (4) (iii) of this section; and

(*c*) In the case of a single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words "from concentrate(s)" shall follow the word "juice(s)" in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (a) (4) (iii) of this section.

(iii) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (a) (4) (ii) (*b*) of this section, such names and the words "from concentrate", as specified in paragraph (a) (4) (ii) (*c*) of this section, shall appear in an ingredient statement pursuant to the requirements of § 101.3(d) of this chapter.

(iv) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(b) *Quality*—(1) The standard of quality for canned fruit cocktail is as follows:

(i) Not more than 20 percent by weight of the units in the container of peach or pear, or of pineapple if the units thereof are diced, are more than ¾ inch in greatest edge dimension, or pass through the meshes of a sieve designated as 5/16 inch in Table I of "Standard Specifications for Sieves," published March 1, 1940, in L.C. 584 of the National Bureau of Standards, United States Department of Commerce. If the units of pineapple are in the form of sectors, not more than 20 percent of such sectors in the container fail to conform to the following dimensions: The length of the outside arc is not more than ¾ inch but is more than ⅜ inch; the thickness is not more than ½ inch but is more than 5/16 inch; the length (measured along the radius from the inside arc to the outside arc) is not more than 1¼ inches but is more than ¾ inch.

(ii) Not more than 10 percent of the grapes in a container containing 10 grapes or more, and not more than 1 grape in a container containing less than 10 grapes, are cracked to the extent of being severed into two parts or are crushed to the extent that their normal shape is destroyed.

(iii) Not more than 10 percent of the grapes in a container containing 10 grapes or more, and not more than a grape in a container containing less than 10 grapes, have the cap stem attached.

(iv) There is present in the finished canned fruit cocktail not more than 1 square inch of pear peel per each 1 pound of drained weight of units of pear plus the weight of a proportion of the packing medium which is the same proportion as the drained weight of the units of pear bears to the drained weight of the entire contents of the can. Such drained weights shall be determined by the method prescribed in paragraph (c) of this section.

(v) There is present in the finished canned fruit cocktail not more than 1 square inch of peach peel per each 1 pound of drained weight of units of peach plus the weight of a proportion of the packing medium which is the same proportion as the drained weight of units of peach bears to the drained weight of the entire contents of the can. Such drained weights shall be determined by the method prescribed in paragraph (c) of this section.

(vi) Not more than 15 percent of the units of cherry ingredient, and not more than 20 percent of the units of peach, pear, or grape, in the container are blemished with scab, hail injury, scar tissue or other abnormality.

(vii) If the cherry ingredient is artificially colored, the color of not more than 15 percent of the units thereof in a container containing more than six units and of not more than one unit in a container containing six units or less, is other than evenly distributed in the unit or other than uniform with the color of the other units of the cherry ingredient.

(2) If the quality of canned fruit cocktail falls below the standard prescribed in paragraph (b) (1) of this section, the label shall bear the general statement of substandard quality specified in § 130.14 (a) of this chapter, in the manner and form therein specified.

(c) *Fill of container*—(1) The standard of fill of container for canned fruit cocktail is a fill such that the total weight of drained fruit is not less than 65 percent of the water capacity of the container, as determined by the general method for water capacity of containers prescribed in § 130.12(a) of this chapter. Such total weight of drained fruit is determined by the following method: Tilt the opened container so as to distribute the contents evenly over the meshes of a circular sieve which has been previously weighed. The diameter of the sieve is 8 inches if the quantity of contents of the container is less than 3 pounds, and 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is woven-wire cloth which complies with the specifications for such cloth set forth under "2380 Micron (No. 8)" in Table I of "Standard Specifications for Sieves," published March 1, 1940, in L.C. 584 of the United States Department of Commerce, National Bureau of Standards. Without shifting the material on the sieve so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and drained fruit. The weight so found, less the weight of the sieve, shall be considered to be the total weight of drained fruit.

(2) If canned fruit cocktail falls below the standard of fill of container prescribed in paragraph (c) (1) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein prescribed.

§ 145.136 Artificially sweetened canned fruit cocktail.

(a) Artificially sweetened canned fruit cocktail is the food which conforms to the definition and standard of identity prescribed for canned fruit cocktail by § 145.135(a), except that in lieu of a packing medium specified in § 145.135(a) (3), the packing medium used is water artificially sweetened with saccharin, sodium saccharin, or a combination of both. Such packing medium may be thickened with pectin and may contain any mixture of any edible organic salt or salts and any edible organic acid or acids as a flavor-enhancing agent, in a quantity not more than is reasonably required for that purpose.

(b) (1) The specified name of the food is "artificially sweetened fruit cocktail".

(2) Artificially sweetened fruit cocktail is subject to the requirements for label statement of optional ingredients used, as prescribed for canned fruit cocktail by § 145.135(a). If the packing medium is thickened with pectin, the label shall bear the statement "thickened with

pectin". When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

§ 145.140 Canned seedless grapes.

(a) *Ingredients.* Canned seedless grapes is the food prepared from one of the fresh or previously canned optional grape ingredients specified in paragraph (b) of this section, which may be packed in one of the optional packing media specified in paragraph (c) of this section. Such food may also contain one, or any combination of two or more, of the following safe and suitable optional ingredients:

(1) Natural and artificial flavors.

(2) Spice.

(3) Vinegar, lemon juice, or organic acids.

Such food is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

(b) *Varietal types and styles.* The optional grape ingredients referred to in paragraph (a) of this section are prepared from stemmed grapes of the light or dark seedless varieties or from unstemmed clusters of such grapes. For the purposes of paragraph (d) of this section, the names of such optional grape ingredients are "light seedless grapes" or "dark seedless grapes", as the case may be, preceded by the words "unstemmed clusters" where applicable.

(c) *Packing media.* (1) The optional packing media referred to in paragraph (a) of this section, as defined in § 145.3 are:

(i) Water.

(ii) Fruit juice(s) and water.

(iii) Fruit juice(s).

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in § 145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in Part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in § 145.3.

(2) When a sweetener is added as a part of any such liquid packing medium, the density range of the resulting packing medium expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure prescribed in § 145.3(m) shall be designated by the appropriate name for the respective density ranges, namely:

(i) When the density of the solution is less than 14 percent, the medium shall be designated as "slightly sweetened water"; or "extra light sirup"; "slightly sweetened fruit juice(s) and water"; or "slightly sweetened fruit juice(s)", as the case may be.

(ii) When the density of the solution is 14 percent or more but less than 18 percent, the medium shall be designated as "light sirup"; "lightly sweetened fruit juice(s) and water"; or "lightly sweetened fruit juice(s)", as the case may be.

(iii) When the density of the solution is 18 percent or more but less than 22 percent, the medium shall be designated as "heavy sirup"; "heavily sweetened fruit juice(s) and water"; or "heavily sweetened fruit juice(s)", as the case may be.

(iv) When the density of the solution is 22 percent or more but not more than 35 percent, the medium shall be designated as "extra heavy sirup"; "extra heavily sweetened fruit juice(s) and water"; or "extra heavily sweetened fruit juice(s)", as the case may be.

(d) *Labeling requirements.* (1) The name of the food is "seedless grapes." The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, "Spice added", or in lieu of the word "Spice", the common name of the spice, or "Seasoned with lemon juice". When two or more of the optional ingredients specified in paragraph (a) (2) and (3) of this section are used, such words may be combined as for example, "Seasoned with cider vinegar, cloves, and cinnamon oil".

(2) The color type and style of the grape ingredient as provided in paragraph (b) of this section and the name of the packing medium specified in paragraph (c) (1) and (2) of this section, preceded by "In" or "Packed in" or the words "solid pack", where applicable, shall be included as part of the name or in close proximity to the name of the food. When the packing medium is prepared with a sweetener(s) which imparts a taste, flavor or other characteristic to the finished food in addition to sweetness, the name of the packing medium shall be accompanied by the name of such sweetener(s), as for example in the case of a mixture of brown sugar and honey, an appropriate statement would be "---------- sirup of brown sugar and honey" the blank to be filled in with the word "light", "heavy", or "extra heavy" as the case may be. When the liquid portion of the packing media provided for in paragraph (c) (1) and (2) of this section consists of fruit juice(s), such juice(s) shall be designated in the packing medium as:

(i) In the case of a single fruit juice, the name of the juice shall be used in lieu of the word "fruit";

(ii) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word "fruit" in the name of the packing medium, or be declared on the label as specified in paragraph (d) (3) of this section; and

(iii) In the case of a single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words "from concentrate(s)" shall follow the word "juice(s)" in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (d) (3) of this section.

(3) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (d) (2) (ii) of this section, such names and the words "from concentrate", as specified in paragraph (d) (2) (iii) of this section, shall appear in an ingredient statement pursuant to the requirements of § 101.3(d) of this chapter.

(4) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 145.145 Canned grapefruit.

(a) *Identity*—(1) *Product identification.* Canned grapefruit is the food prepared from one of the optional grapefruit ingredients specified in paragraph (a) (2) of this section and one of the optional packing media specified in paragraph (a) (3) of this section. Such food may also contain one or more of the following safe and suitable optional ingredients:

(i) Spices.

(ii) Natural and artificial flavoring.

(iii) Lemon juice.

(iv) Citric acid.

(v) Calcium chloride or calcium lactate or a mixture of the two calcium salts in a quantity reasonably necessary to firm the grapefruit sections, but in no case in a quantity such that the calcium contained in such calcium salt or mixture is more than 0.035 percent by weight of the finished food.

Such food is sealed in a container and, before or after sealing, is so processed by heat as to prevent spoilage.

(2) *Optional grapefruit ingredient.* The optional grapefruit ingredients referred to in paragraph (a) (1) of this section are prepared from sound, mature grapefruit (*Citrus paradisi* Macfadyen) of the color types white—produced from white-fleshed grapefruit, and pink—produced from pink or red-fleshed grapefruit and are in the following forms of units: Whole sections or broken sections. Each such form of units or a mixture of such forms of units prepared from a single varietal group (color type) is an optional grapefruit ingredient. The core, seeds, and major portions of membrane of such ingredient are removed. For the purpose of this section, a grapefruit section is considered whole when the unit is intact or an intact portion of such unit is not less than 75 percent of its apparent original size and is not excessively trimmed.

(i) For the purpose of paragraph (a) (4) of this section, the name of the optional grapefruit ingredient is:

(a) "Section" or "segments", if 50 percent or more of the drained weight of the food consists of whole sections.

(b) "Broken sections" or "broken segments", if less than 50 percent of the

drained weight of the food consists of whole sections.

(ii) The drained weight is determined by the method prescribed in the standard of fill of container for canned grapefruit set forth in paragraph (c)(2) of this section.

(3) *Packing media.* (i) The optional packing media referred to in paragraph (a)(1) of this section are:

(*a*) Water.

(*b*) Grapefruit juice and water.

(*c*) Grapefruit juice.

(*d*) Slightly sweetened sirup or slightly sweetened water.

(*e*) Light sirup.

(*f*) Heavy sirup.

(*g*) Slightly sweetened grapefruit juice and water.

(*h*) Lightly sweetened grapefruit juice and water.

(*i*) Heavily sweetened grapefruit juice and water.

(*j*) Slightly sweetened grapefruit juice.

(*k*) Lightly sweetened grapefruit juice.

(*l*) Heavily sweetened grapefruit juice.

As used in paragraph (a)(3)(i) of this section, the optional packing medium "water" means, in addition to water, any mixture of water and grapefruit juice in which there is less than 50 percent grapefruit juice; the optional packing medium "grapefruit juice and water" means the liquid packing medium in which juice of mature grapefruit and water are combined as a liquid packing medium with not less than 50 percent grapefruit juice and the term "grapefruit juice" means single strength expressed juice of sound, mature fruit. It may be fresh, canned, or made from concentrate. However, if it is made from concentrate, the juice shall be reconstituted with water to not less than the soluble solids the grapefruit juice had before concentration.

(ii) Each of the packing media in paragraph (a)(3)(i) (*d*) to (*l*) of this section is prepared with a liquid ingredient and one or more safe and suitable nutritive carbohydrate sweeteners. Water is the liquid ingredient from which packing media in paragraph (a)(3)(i) (*d*) to (*f*) of this section are prepared. Grapefruit juice and water are the liquid ingredients from which the packing media in paragraph (a)(3)(i) (*g*) to (*i*) of this section are prepared. Grapefruit juice is the liquid ingredient from which the packing media in paragraph (a)(3)(i) (*j*) to (*l*) of this section are prepared. If one or more liquid nutritive carbohydrate sweeteners and grapefruit juice are combined as a liquid packing medium with not less than 50 percent grapefruit juice, the packing medium is as set forth in paragraph (a)(3)(i) (*g*) to (*i*) of this section.

(iii) The respective densities of packing media in paragraph (a)(3)(i) (*d*) to (*i*) of this section as measured on the refractometer, expressed as percent by weight sucrose (degrees Brix) with correction for temperature to the equivalent at 20° C (68° F), 15 days or more after the grapefruit are canned or the blended homogenized slurry of the comminuted entire contents of the container if canned for less than 15 days, according to the "Official Methods of Analysis of the Association of Official Analytical Chemists",[2] 11th Ed., 1970, page 526, section 31.011 (Solids) "By Means of Refractometer—Official Final Action" (and 47.012 and 47.015) without correction for invert sugar or other substances, are as follows:

(*a*) Packing media in paragraph (a)(3)(i) (*d*), (*g*), and (*j*) of this section: Twelve percent or more but less than 16 percent.

(*b*) Packing media in paragraph (a)(3)(i) (*e*), (*h*), and (*k*) of this section: Sixteen percent or more but less than 18 percent.

(*c*) Packing media in paragraph (a)(3)(i) (*f*), (*i*), and (*l*) of this section: Eighteen percent or more. A lot shall be deemed to be in compliance for packing medium density based on the average value for all the samples analyzed according to paragraph (b)(2) of this section but no container may have a value lower than that of the next lower category or 2 percent by weight sucrose (degrees Brix) lower if no lower category exists.

(4) *Labeling requirements.* (i) The name of the food is "grapefruit" or "pink grapefruit", as appropriate for the color type of the grapefruit used. The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, "with added spice". Whenever the word "sirup" is used, it may be alternatively spelled "syrup". When two or more of the optional ingredients specified in paragraphs (a)(1)(i), (ii), and (iii) of this section are used, such words may be combined; for example, "with added cloves and cinnamon oil".

(ii) The form and style of the grapefruit ingredient as provided for in paragraph (a)(2) of this section and the name of the packing medium as used in paragraph (a)(3) of this section preceded by "In" or "Packed in" shall be included as part of the name. When the packing medium is prepared from concentrated grapefruit juice, the words "from concentrate" shall follow the words "grapefruit juice" in the name of the packing medium.

(iii) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(b) *Quality*—(1) The standard of quality for canned grapefruit is as follows:

(i) The food is free from extraneous material such as leaves, portions of leaves, and pieces of peel.

(ii) The finished food contains per 500 grams (17.6 ounces) not more than:

(*a*) An aggregate area of 20 square centimeters (3.1 square inches) of tough membrane or albedo on the units.

(*b*) Four developed seeds. A seed is considered a developed seed when it measures more than 9.0 millimeters (0.35 inches) in any dimension.

(iii) Not more than 15 percent by weight of the drained grapefruit may be blemished units. A blemished unit is a grapefruit section or any portion thereof which is damaged by lye peeling, by discoloration, or by other visible injury. The drained weight is determined by the method prescribed in the standard of fill of container for canned grapefruit set forth in paragraph (c)(2) of this section.

(2) *Sampling and acceptance procedure.* A lot is to be considered acceptable when the number of "defectives" does not exceed the acceptance number in the sampling plans given in paragraph (b)(2)(ii) of this section.

(i) Definitions of terms to be used in the sampling plans in paragraph (b)(2)(ii) of this section are as follows:

(*a*) *Lot.* A collection of primary containers or units of the same size, type and style manufactured or packed under similar conditions and handled as a single unit of trade.

(*b*) *Lot size.* The number of primary containers or units in the lot.

(*c*) *Sample size* (*n*). The total number of sample units drawn for examination from a lot.

(*d*) *Sample unit.* A container, the entire contents of a container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for the examination or testing as a single unit.

(*e*) *Defective.* Any sample unit shall be regarded as defective when any of the defects or conditions specified in the quality standard (paragraph (b)(1) of this section) and paragraph (c)(3)(i) of this section for minimum fill of container are present in excess of the stated tolerances.

(*f*) *Accepted number* (*c*). The maximum number of defective sample units permitted in the sample in order to consider the lot as meeting the specified requirements.

(*g*) *Acceptable quality level* (*AQL*). The maximum percent of defective sample units permitted in a lot that will be accepted approximately 95 percent of the time.

[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

(ii) Sampling plans and acceptance procedure:

Lot size (primary containers)	Size of container	
	Net weight equal to or less than 1 kg (2.2 lb)	
	n	c
4,800 or less	13	2
4,801–24,000	21	3
24,001–48,000	29	4
48,001–84,000	48	6
84,001–144,000	84	9
144,001–240,000	126	13
over 240,000	200	19
	Net weight greater than 1 kg (2.2 lb) but not more than 4.5 kg (10 lb)	
	n	c
2,400 or less	13	2
2,401–15,000	21	3
15,001–24,000	29	4
24,001–42,000	48	6
42,001–72,000	84	9
72,001–120,000	126	13
over 120,000	200	19
	Net weight greater than 4.5 kg (10 lb)	
	n	c
600 or less	13	2
601–2,000	21	3
2,001–7,200	29	4
7,201–15,000	48	6
15,001–24,000	84	9
24,001–42,000	126	13
over 42,000	200	19

n=number of primary containers in sample
c=acceptance number

(3) If the quality of canned grapefruit falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in § 130.14(a) of this chapter, in the manner and form therein specified; however, if the quality of the canned grapefruit falls below standard with respect to only one of the factors of quality specified by paragraph (b)(1)(i), (ii), or (iii) of this section, there may be substituted for the second line of such general statement of substandard quality, "Good Food—Not High Grade", a new line as specified after the corresponding designation of paragraph (b)(1) of this section which the canned grapefruit fail to meet:

(i) "Contains extraneous material".

(ii) (*a*) "Excessive tough membrane".

(*b*) "Excessive seeds".

(iii) "Excessive blemished units".

(c) *Fill of container*—(1) The standard of fill of container for canned grapefruit is:

(i) The fill of grapefruit and packing medium, as determined by the general method for fill of container prescribed in § 130.12(b) of this chapter, is not less than 90 percent of the total capacity of the container.

(ii) The drained weight of grapefruit ingredient is not less than 50 percent of the water capacity of the container, as determined by the method prescribed in paragraph (c)(2) of this section and the general method for water capacity of containers prescribed in § 130.12(a) of this chapter.

(2) Drained weight is determined by the following method: Tilt the opened container so as to distribute the contents evenly over the meshes of a circular sieve which has previously been weighed. The diameter of the sieve is 20.3 centimeters (8 inches) if the quantity of contents of the container is less than 1.4 kilograms (3 pounds) and 30.5 centimeters (12 inches) if such quantity is 1.4 kilograms (3 pounds) or more. The bottom of the sieve is woven-wire cloth which complies with the specifications for the No. 8 sieve set forth in the "Definitions of Terms and Explanatory Notes," page xviii, of the "Official Methods of Analysis of the Association of Official Analytical Chemists",[*] 11th Ed., 1970. Without shifting the material on the sieve, incline the sieve at an angle of 17° to 20° to facilitate drainage. Two minutes after the drainage begins, weigh the sieve and drained grapefruit. The weight so found, less the weight of the sieve, shall be considered to be the weight of the drained grapefruit.

(3)(i) A container that falls below the requirement for minimum fill prescribed in paragraph (c)(1)(i) of this section shall be considered a "defective". The food will be deemed to fall below the standard of fill when the number of defectives exceeds the acceptance number (c) in the sampling plans prescribed in paragraph (b)(2) of this section.

(ii) Canned grapefruit will be deemed to fall below the standard of fill when the average drained weight of all containers analyzed when sampled according to the sampling plans prescribed in paragraph (b)(2) of this section is less than that prescribed in paragraph (c)(1)(ii) of this section.

(4) If canned grapefruit falls below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

§ 145.170 Canned peaches.

(a) *Identity*—(1) *Ingredients.* Canned peaches is the food prepared from one of the fresh, frozen, or previously canned optional peach ingredients *Prunus persica* L., of commercial canning varieties, but excluding nectarine varieties, specified in paragraph (a)(2) of this section, which may be packed as a solid pack or in one of the optional packing media specified in paragraph (a)(3) of this section. Such food may also contain one, or any combination of two or more, of the following safe and suitable optional ingredients:

(i) Natural and artificial flavors.

(ii) Spice.

(iii) Vinegar, lemon juice, or organic acids.

(iv) Peach pits, except in the cases of peeled whole peaches, in a quantity not more than 1 peach pit to each 227 grams (8 ounces) of finished canned peaches.

(v) Peach kernels, except in the cases of peeled whole peaches and except when the optional ingredient in paragraph (a)(1)(iv) of this section is used.

(vi) Ascorbic acid in an amount no greater than necessary to preserve color. Such food is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

(2) *Varietal types and styles.* The optional peach ingredients referred to in paragraph (a)(1) of this section are prepared from mature peaches of the following optional varietal and color types and styles of peach ingredients; namely:

(i) *The optional varietal types.* (*a*) Freestone is the distinct varietal type where the pit separates readily from the flesh.

(*b*) Clingstone is the distinct varietal type where the pit adheres to the flesh.

(ii) *The optional color types*—(*a*) *Yellow*—the varietal types in which the predominant color ranges from pale yellow to rich red orange.

(*b*) *White*—the varietal types in which the predominant color ranges from white to yellow-white.

(*c*) *Red*—the varietal types in which the predominant color ranges from pale yellow to orange red and with variegated red coloring other than that associated with the pit cavity.

(*d*) *Green*—varietal types in which the flesh has a green tint even when mature.

(iii) *The optional styles of the peach ingredients*—(*a*) *Whole*—Consisting of whole peeled unpitted peaches.

(*b*) *Halves*—consisting of peeled pitted peaches cut into two approximately equal parts.

(*c*) *Halves and pieces*—consisting of a mixture in which the halves will be more than 50 percent by weight.

(*d*) *Quartered*—consisting of peeled pitted peaches cut into four approximately equal parts.

(*e*) *Sliced*—consisting of peeled pitted peaches cut into wedge-shaped sectors.

(*f*) *Diced*—consisting of peeled pitted peaches cut into cube-like parts.

(*g*) *Pieces or irregular pieces*—consisting of peeled pitted peaches of irregular shapes and sizes.

(3) *Packing media.* (i) The optional packing media referred to in paragraph (a)(1) of this section, as defined in § 145.3 are:

(*a*) Water.

(*b*) Fruit juice(s) and water.

(*c*) Fruit juice(s).

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in § 145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in Part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in § 145.3.

(ii) When a sweetener is added as a part of any such liquid packing medium, the density range of the resulting packing medium, expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure prescribed in § 145.3(m), shall be designated by the

[*] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

appropriate name for the respective density ranges, namely:

(*a*) When the density of the solution is 10 percent or more but less than 14 percent, the medium shall be designated as "slightly sweetened water"; or "extra light sirup"; "slightly sweetened fruit juice(s) and water"; or "slightly sweetened fruit juice(s)", as the case may be.

(*b*) When the density of the solution is 14 percent or more but less than 18 percent, the medium shall be designated as "light sirup"; "lightly sweetened fruit juice(s) and water"; or "lightly sweetened fruit juice(s)", as the case may be.

(*c*) When the density of the solution is 18 percent or more but less than 22 percent, the medium shall be designated as "heavy sirup"; "heavily sweetened fruit juice(s) and water"; or "heavily sweetened fruit juice(s)", as the case may be.

(*d*) When the density of the solution is 22 percent or more but not more than 35 percent, the medium shall be designated as "extra heavy sirup"; "extra heavily sweetened fruit juice(s) and water"; or "extra heavily sweetened fruit juice(s)", as the case may be.

(4) *Labeling requirements.* (i) The name of the food is "peaches". The optional varietal type as set forth in paragraph (a)(2)(i) of this section shall be a part of the name. The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, "Spice added", or in lieu of the word "Spice", the common name of the spice, "Seasoned with vinegar" or "Seasoned with peach kernels". When two or more of the optional ingredients specified in paragraph (a)(1)(ii) through (v) of this section are used, such words may be combined as for example, "Seasoned with cider vinegar, cloves, cinnamon oil and peach kernels".

(ii) The color type and style of the peach ingredient as provided in paragraph (a)(2)(ii) and (iii) of this section and the name of the packing medium specified in paragraph (a)(3)(i) and (ii) of this section, preceded by "In" or "Packed in" or the words "solid pack", where applicable, shall be included as part of the name or in close proximity to the name of the food, except that pieces or irregular pieces shall be designated "Pieces", "Irregular pieces", or "Mixed pieces of irregular sizes and shapes". "Halves" may be alternately designated as "Halved", "Halves and pieces" as "Halved and pieces", "Quartered" as "Quarters", "Sliced" as "Slices", and "Diced" as "Dice". The terms "Cling" and "Free" may be used as optional designations for "Clingstone" and "Freestone" respectively. When the packing medium is prepared with a sweetener(s) which imparts a taste, flavor, or other characteristic to the finished food in addition to sweetness, the name of the packing medium shall be accompanied by the name of such sweetener(s), as for example in the case of a mixture of brown sugar and honey, an appropriate statement would be "_____ sirup of brown sugar and honey" the blank to be filled in with the word "light", "heavy", or "extra heavy" as the case may be. When the liquid portion of the packing media provided for in paragraph (a)(3)(i) and (ii) of this section consists of fruit juice(s), such juice(s) shall be designated in the name of the packing medium as:

(*a*) In the case of a single fruit juice, the name of the juice shall be used in lieu of the word "fruit";

(*b*) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word "fruit" in the name of the packing medium, or be declared on the label as specified in paragraph (a)(4)(iii) of this section; and

(*c*) In the case of a single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words "from concentrate(s)" shall follow the word "juice(s)" in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (a)(4)(iii) of this section.

(iii) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (a)(4)(ii)(*b*) of this section, such names and the words "from concentrate", as specified in paragraph (a)(4)(ii)(*c*) of this section, shall appear in an ingredient statement pursuant to the requirements of § 101.3(d) of this chapter.

(iv) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(b) *Quality*—(1) The standard of quality for canned peaches is as follows:

(i) All units tested in accordance with the method prescribed in paragraph (b) of this section are pierced by a weight of not more than 300 grams.

(ii) In the cases of halves and quarters, the weight of each unit is not less than ⅗ ounce and 3/10 ounce, respectively.

(iii) In the cases of whole peaches, halves, and quarters, the weight of the largest unit in the container is not more than twice the weight of the smallest unit therein.

(iv) Except in the case of unpeeled peaches, there is present in the finished canned peaches not more than 1 square inch of peel per each 1 pound of net contents.

(v) Not more than 20 percent of the units in the container are blemished with scab, hail injury, discoloration, or other abnormalities.

(vi) In the cases of whole peaches, halves, quarters, and slices, all units are untrimmed, or are so trimmed as to preserve normal shape.

(vii) Except in the case of mixed pieces of irregular sizes and shapes, not more than 5 percent of the units in a container of 20 or more units, and not more than one unit in a container of less than 20 units, are crushed or broken. (A unit which has lost its normal shape because of ripeness and which bears no mark of crushing shall not be considered to be crushed or broken.)

(2) Canned peaches shall be tested by the following method to determine whether or not they meet the requirements of paragraph (b)(1)(i) of this section: So trim a test piece from the unit as to fit, with peel surface up, into a supporting receptacle. If the unit is of different firmness in different parts of its peel surface, trim the piece from the firmest part. If the piece is unpeeled, remove the peel. The top of the receptacle is circular in shape, of 1⅛ inches inside diameter, with vertical sides; or rectangular in shape, ¾ inch by 1 inch inside measurements, with ends vertical and sides sloping downward and joining at the center at a vertical depth of ¾ inch. Use the circular receptacle for testing units of such size that a test piece can be trimmed therefrom to fit it. Use the rectangular receptacle for testing other units. Test no unit from which a test piece with rectangular peel surface at least ½ inch by 1 inch cannot be trimmed. Test the piece by means of a round metal rod 5/32 inch in diameter. To the upper end of the rod is affixed a device to which weight can be added. The rod is held vertically by a support through which it can freely move upward or downward. The lower end of the rod is a plane surface to which the vertical axis of the rod is perpendicular. Adjust the combined weight of the rod and device to 100 grams. Set the receptacle so that the surface of the test piece is held horizontally. Lower the end of the rod to the approximate center of such surface, and add weight to the device at a uniform, continuous rate of 12 grams per second until the rod pierces the test piece. Weigh the rod and weighted device. Test all units in containers of 50 units or less, except those units too small for testing or too soft for trimming. Test at least 50 units, taken at random, in containers of more than 50 units; but if less than 50 units are of sufficient size and firmness for testing, test those which are of sufficient size and firmness.

(3) If the quality of canned peaches falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in § 130.14(a) of this chapter, in the manner and form therein specified: but in lieu of such general statement of substandard quality the label may bear the alternative statement "Below Standard in Quality _____", the blank to be filled in with the words specified after the corresponding number of each clause of paragraph (b)(1) of this section which such canned peaches fail to meet, as follows: (i) "Not tender"; (ii) "Small halves," or "Small quarters", as the case may be; (iii) "Mixed Sizes"; (iv) "Not well peeled"; (v) "Blemished"; (vi) "Unevenly trimmed"; (vii) "Partly crushed or broken". Such alternative statement shall immediately and conspicuously precede or follow, without intervening written, printed, or graphic matter, the name "peaches" and any words and statements required or authorized to ap-

pear with such name by paragraph (a)(2) of this section.

(c) *Fill of container*—(1) The standard of fill of container for canned peaches is the maximum quantity of the optional peach ingredient that can be sealed in the container and processed by heat to prevent spoilage, without crushing or breaking such ingredient.

(2) If canned peaches fall below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in § 130.14 (b) of this chapter, in the manner and form therein specified.

§ 145.171 Artificially sweetened canned peaches.

(a) Artificially sweetened canned peaches is the food which conforms to the definition and standard of identity prescribed for canned peaches by § 145.170(a), except that in lieu of a packing medium specified in § 145.170(a)(3), the packing medium used is water artificially sweetened with saccharin, sodium saccharin, or a combination of both. Such packing medium may be thickened with pectin and may contain any mixture of any edible organic salt or salts and any edible organic acid or acids as a flavor-enhancing agent, in a quantity not more than is reasonably required for that purpose.

(b)(1) The specified name of the food is "artificially sweetened _____", the blank being filled in with the name prescribed by § 145.170(a) for canned peaches having the same optional peach ingredient.

(2) The artificially sweetened food is subject to the requirements for label statement of optional ingredients used, as prescribed for canned peaches by § 145.170(a). If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin". When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

§ 145.173 Canned peaches with rum.

Canned peaches with rum conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for canned peaches by § 145.170(a) except that it contains added rum in such amount that its alcohol content is more than 3 percent but less than 5 percent by weight.

§ 145.175 Canned pears.

(a) *Identity*—(1) *Ingredients.* Canned pears is the food prepared from one of the fresh or previously canned optional pear ingredients *Pyrus communis* or *Pyrus sinensis* specified in paragraph (a)(2) of this section which may be packed in one of the optional packing media specified in paragraph (a)(3) of this section. Such food may also contain one, or any combination of two or more, of the following safe and suitable optional ingredients.

(i) Natural and artificial flavors.

(ii) Spice.

(iii) Vinegar, lemon juice, or organic acids.

(iv) Artificial colors.

Such food is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

(2) *Styles and forms of units.* The optional pear styles and forms of units referred to in paragraph (a)(1) of this section are:

(i) Whole.
(ii) Halves.
(iii) Quarters.
(iv) Slices.
(v) Diced.
(vi) Pieces or irregular pieces.

Each such ingredient is peeled, except whole and halves may be, alternatively, unpeeled. Except in the case of whole pears, each such ingredient is cored.

(3) *Packing media.* (i) The optional packing media referred to in paragraph (a)(1) of this section, as defined in § 145.3 are:

(*a*) Water.
(*b*) Fruit juice(s) and water.
(*c*) Fruit juice(s).
(*d*) Clarified juice.

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in § 145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in Part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in § 145.30.

(ii) If the concentration of clarified juice is such that the packing medium forms to the density range for one of the sirups under paragraph (a)(3)(ii)(*a*), (*b*), (*c*), or (*d*) of this section, the concentrated clarified juice is considered to be light sirup, heavy sirup, or extra heavy sirup, as the case may be. When a sweetener is added as a part of any such liquid packing medium, the density range of the resulting packing medium expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure in § 145.3(m) shall be designated by the appropriate name for the respective density ranges, namely:

(*a*) When the density of the solution is less than 14 percent, the medium shall be designated as "slightly sweetened water"; or "extra light sirup"; "slightly sweetened fruit juice(s) and water"; or "slightly sweetened fruit juice(s)", as the case may be.

(*b*) When the density of the solution is 14 percent or more but less than 18 percent, the medium shall be designated as "light sirup"; "lightly sweetened fruit juice(s) and water"; or "lightly sweetened fruit juice(s)" as the case may be.

(*c*) When the density of the solution is 18 percent or more but less than 22 percent, the medium shall be designated as "heavy sirup"; "heavily sweetened fruit juice(s) and water"; or "heavily sweetened fruit juice(s)", as the case may be.

(*d*) When the density of the solution is 22 percent or more but not more than 35 percent, the medium shall be designated as "extra heavy sirup"; "extra heavily sweetened fruit juice(s) and water"; or "extra heavily sweetened fruit juice(s)", as the case may be.

(4) *Labeling requirements.* (i) The name of the food is "pears". The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, "Spice Added", or in lieu of the word "Spice", the common name of the spice, "Seasoned with Vinegar". When two or more of the optional ingredients specified in paragraph (a)(1)(ii) and (iii) of this section are used, such words may be combined as for example, "Seasoned with cider vinegar, cloves, and cinnamon oil".

(ii) The style and forms of units of the pear ingredient as provided in paragraph (a)(2) of this section and the name of the packing medium specified in paragraph (a)(3)(i) and (ii) of this section, preceded by "In" or "Packed in" or the words "solid pack", where applicable, shall be included as part of the name or in close proximity to the name of the food, except that pieces or irregular pieces shall be designated "Pieces", "Irregular pieces", or "Mixed pieces of irregular sizes and shapes". The style of the pear ingredient shall be preceded or followed by "Unpeeled" when the units are whole or halves and are unpeeled. "Halves" may be alternatively designated as "Halved", "Quarters" as "Quartered", "Slices" as "Sliced", and "Diced" as "Dice". When the packing medium is prepared with a sweetener(s) which imparts a taste, flavor or other characteristic to the finished food in addition to sweetness, the name of the packing medium shall be accompanied by the name of such sweetener(s), as for example in the case of a mixture of brown sugar and honey, an appropriate statement would be "_____ sirup of brown sugar and honey" the blank to be filled in with the word "light", "heavy", or "extra heavy", as the case may be. When the liquid portion of the packing media provided for in paragraph (a)(3)(i) and (ii) of this section consists of fruit juice(s), such juice(s) shall be designated in the name of the packing medium as:

(*a*) In the case of a single fruit juice, the name of the juice shall be used in lieu of the word "fruit";

(*b*) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word "fruit" in the name of the packing medium, or be declared on the label as specified in paragraph (a)(4)(iii) of this section; and

(*c*) In the case of a single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words "from concentrate(s)" shall follow the word "juice(s)" in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (a)(4)(iii) of this section.

(iii) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (a)(4)(ii)(b) of this section, such names and the words "from concentrate", as specified in paragraph (a)(4)(ii)(c) of this section, shall appear in an ingredient statement pursuant to the requirements of § 101.3(d) of this chapter.

(iv) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(b) *Quality*—(1) The standard of quality for canned pears is as follows:

(i) All units tested in accordance with the method prescribed in paragraph (b)(2) of this section are pierced by a weight of not more than 300 grams.

(ii) In the cases of halves and quarters, the weight of each unit is not less than ⅝ ounce and 3/10 ounce, respectively.

(iii) In the cases of whole pears, halves, and quarters, the weight of the largest unit in the container is not more than twice the weight of the smallest unit therein.

(iv) Except in the case of unpeeled pears, there is present in the finished canned pears not more than 1 square inch of peel per each 1 pound of net contents.

(v) Not more than 20 percent of the units in the container are blemished with scab, hail injury, discoloration, or other abnormalities.

(vi) In the cases of whole pears, halves, and quarters, all units are untrimmed, or are so trimmed as to preserve normal shape.

(vii) Except in the case of mixed pieces of irregular sizes and shapes, not more than 10 percent of the units in a container of 10 or more units, and not more than 1 unit in a container of less than 10 units, are crushed or broken. (A unit which has lost its normal shape because of ripeness and which bears no mark of crushing shall not be considered to be crushed or broken.)

(2) Canned pears shall be tested by the following method to determine whether or not they meet the requirements of paragraph (a)(1) of this section: So trim a test piece from the unit as to fit, with peel surface up, into a supporting receptacle. If the unit is of different firmness in different parts of its peel surface, trim the piece from the firmest part. If the piece is unpeeled remove the peel. The top of the receptacle is circular in shape of 1⅛ inches inside diameter, with vertical sides; or rectangular in shape, ¾ inch by 1 inch inside measurements, with ends vertical and sides sloping downward and joining at the center at a vertical depth of ¾ inch. Use the circular receptacle for testing units of such size that a test piece can be trimmed therefrom to fit it. Use the rectangular receptable for testing other units. Test no unit from which a test piece with rectangular peel surface at least ½ inch by 1 inch cannot be trimmed. Test the piece by means of a round metal rod 9/32 inch in diameter. To the upper end of the rod is affixed a device to which weight can be added. The rod is held vertically by a support through which it can freely move upward or downward. The lower end of the rod is a plane surface to which the vertical axis of the rod is perpendicular. Adjust the combined weight of the rod and device to 100 grams. Set the receptacle so that the surface of the test piece is held horizontally. Lower the end of the rod to the approximate center of such surface, and add weight to the device at a uniform, continuous rate of 12 grams per second until the rod pierces the test piece. Weigh the rod and weighted device. Test all units in containers of 50 units or less, except those units too small for testing or too soft for trimming. Test at least 50 units, taken at random, in containers of more than 50 units; but if less than 50 units are of sufficient size and firmness for testing, test those which are of sufficient size and firmness.

(3) If the quality of canned pears falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in § 130.14(a) of this chapter in the manner and form therein specified; but in lieu of such general statement of substandard quality, the label may bear the alternative statement "Below standard in quality ____", the blank to be filled in with the words specified after the corresponding number of each subparagraph of paragraph (a) of this section which such canned pears fail to meet, as follows: (i) "Not tender"; (ii) "Small halves" or "Small quarters," as the case may be; (iii) "Mixed sizes"; (iv) "Not well peeled"; (v) "Blemished"; (vi) "Unevenly trimmed"; (vii) "Partly crushed or broken". Such alternative statement shall immediately and conspicuously precede or follow, without intervening written, printed, or graphic matter, the name "pears" and any words and statements required or authorized to appear with such names by paragraph (a)(2) of this section.

(c) *Fill of container*—(1) The standard of fill of container for canned pears is the maximum quantity of the optional pear ingredient that can be sealed in the container and processed by heat to prevent spoilage, without crushing or breaking such ingredient.

(2) If canned pears fall below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

§ 145.176 Artificially sweetened canned pears.

(a) Artificially sweetened canned pears is the food which conforms to the definition and standard of identity prescribed for canned pears by § 145.175(a) except that in lieu of a packing medium specified in § 145.175(a)(3), the packing medium used is water artificially sweetened with saccharin, sodium saccharin, or a combination of both. Such packing medium may be thickened with pectin and may contain any mixture of any edible organic salt or salts and any edible organic acid or acids as a flavor-enhancing agent, in a quantity not more than is reasonably required for that purpose.

(b) (1) The specified name of the food is "artificially sweetened _____", the blank being filled in with the name prescribed by § 145.175(a) for canned pears having the same optional pear ingredient.

(2) The artificially sweetened food is subject to the requirements for label statement of optional ingredients used, as prescribed for canned pears by § 145.175(a). If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin". When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

§ 145.178 Canned pears with rum.

Canned pears with rum conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for canned pears by § 145.175(a), except that it contains added rum in such amount that its alcohol content is more than 3 percent but less than 5 percent by weight.

§ 145.180 Canned pineapple.

(a) *Identity*—(1) Canned pineapple is the food prepared from one of the following optional forms of units obtained from peeled, cored, mature fruits of the pineapple plant:

(i) Sliced, slices; consisting of whole circular slices cut across the axis of the peeled, cored fruit cylinders.

(ii) Half sliced, half slices; consisting of semicircular halves of slices. A unit that is approximately one-half slice is considered to be a half slice.

(iii) Broken sliced, broken slices; consisting of arc-shaped portions cut or broken from slices, which portions are not uniform in size or shape.

(iv) Tidbits; consisting of sectors cut from slices. Tidbits are reasonably uniform in size and shape; they are predominantly from 5/16-inch to ½-inch thick and, except for an occasional unit, each sector is not larger than one-sixth of the slice from which cut.

(v) Chunks; consisting of short, thick pieces cut from thick slices or from peeled, cored fruit. Chunks may or may not be symmetrical or uniform in shape and size. Predominantly, the units have a thickness greater than ½-inch, a width greater than 9/16-inch, but a longest dimension (along any edge) not greater than 1½ inches.

(vi) Cubes, diced; consisting of cube-shaped pieces cut from slices or from peeled, cored fruit. Except for an occasional unit, the longest dimension (along any edge) of each unit is not greater than 9/16-inch.

(vii) Spears, fingers; consisting of long, slender pieces cut parallel to the core axis from peeled cored fruit cylinders. The units are not larger than one-sixth of the cylinder from which they are cut, and they are not less than 2½ inches long.

(viii) Crushed; consisting of shredded or finely cut pieces of fruit flesh.

The optional forms of units specified by paragraphs (a) (1) (i) through (vii) of this section are canned with one of the optional packing media specified in paragraph (a) (2) of this section. The optional form of unit specified by paragraph (a) (1) (viii) of this section may be canned with one of the optional packing media specified in paragraph (a) (2) (ii) through (vi) of this section or with one of the optional sweetening ingredients specified in paragraph (a) (4) of this section. Canned pineapples may be flavored or seasoned with one or more of the optional ingredients specified in paragraph (a) (5) of this section. In the canning of pineapple, dimethylpolysiloxane complying with the requirements of § 173.340 of this chapter may be employed as a defoaming agent in an amount not greater than 10 parts per million by weight of the finished food. Such food is sealed in containers, and is so processed by heat, either before or after sealing, as to prevent spoilage.

(2) The optional packing media referred to in paragraph (a) (1) of this section are:

(i) Water.

(ii) Pineapple juice.

(iii) Clarified juice.

(iv) Light sirup.

(v) Heavy sirup.

(vi) Extra heavy sirup.

(3) For the purposes of this section:

(i) Pineapple juice conforms to the definition and standard of identity for unsweetened pineapple juice as specified in § 146.185(a) of this chapter, except that it is not required to be separately sealed in containers and so processed by heat as to prevent spoilage. Clarified juice is the liquid collected from cutting various form of units from pineapple fruits, or the liquid expressed wholly or in part from pineapple cores, shells, or from pineapple flesh or parts thereof, which liquid is clarified and may be further refined or concentrated; but if the concentration is such that the packing medium conforms to the density range for one of the sirups hereinafter specified, such concentrated liquid is considered to be light sirup, heavy sirup, or extra heavy sirup, as the case may be.

(ii) Except as the concentrated clarified juice is considered to be a sirup packing medium as above provided, each of the packing media light sirup, heavy sirup and extra heavy sirup consist of an optional sweetening ingredient as specified in paragraph (a) (4) of this section, dissolved in one or any mixture of two or more of the liquids designated in paragraphs (a) (2) (i), (ii), and (iii) of this section. The sirup packing media have respective densities as determined by the method specified in "Official Methods of Analysis of the Association of Official Agricultural Chemists," Eighth Edition, on page 533, under the heading "Solids—By Means of Spindle—Official," [Ed. note 10th edition 1965, p. 486, sec. 29.009], using the Brix hydrometer 15 days or more after the pineapple is canned, which are within the ranges specified for each in the following list:

Packing medium	*Brix measurement*
Light sirup	14° or more but less than 18°.
Heavy sirup	18° or more but less than 22°.
Extra heavy sirup	22° or more but not more than 35°.

(iii) In the case of crushed pineapple (paragraph (a) (1) (viii) of this section), the juice resulting from cutting or shredding the pineapple flesh is considered to be pineapple juice, without regard to whether it has or has not been drained away from the pieces of pineapple.

(4) The optional sweetening ingredients referred to in paragraphs (a) (1) and (3) of this section are:

(i) Sugar.

(ii) Invert sugar sirup.

(iii) Any mixture of optional sweetening ingredients designated in paragraph (a) (4) (i) and (ii) of this section.

(iv) Any of the optional sweetening ingredients designated in paragraph (a) (4) (i), (ii), and (iii) of this section with dextrose, provided that the weight of the solids of dextrose does not exceed one-third of the total weight of the solids of the combined sweetening ingredients.

(v) Any of the optional sweetening ingredients designated in paragraph (a) (4) (i), (ii), and (iii) of this section with corn sirup or with dried corn sirup or with glucose sirup or with dried glucose sirup, or with any two or more of these, provided that the weight of the solids of corn sirup, dried corn sirup, glucose sirup, dried glucose sirup or the sum of the weights of the solids of corn sirup, dried corn sirup, glucose sirup, and dried glucose sirup, in case two or more of these are used, does not exceed one-fourth of the total weight of the solids of the combined sweetening ingredients.

(vi) Any mixture of the optional ingredients designated in paragraph (a) (4) (iv) and (v) of this section.

(5) The optional ingredients referred to in paragraph (a) (1) of this section are as follows:

(i) Spice.

(ii) Flavoring, other than artificial flavoring.

(iii) A vinegar.

(6) The name of the canned pineapple prepared from each of the optional forms of pineapple ingredient specified in paragraph (a) (1) of this section is as follows:

(i) If the optional form is one designated in paragraph (a) (1) (i) to (vii), inclusive, of this section, the name is "pineapple", preceded or followed, for each of the indicated optional forms of units, by the words here specified:

(*a*) "Sliced" or "slices".

(*b*) "Half sliced" or "half slices".

(*c*) "Broken sliced" or "broken slices".

(*d*) "Tidbits".

(*e*) "Chunks".

(*f*) "Cubes" or "diced".

(*g*) "Spears" or "fingers".

(ii) If the optional form is one designated in paragraph (a) (1) (viii) of this section, the name is "pineapple", preceded or followed by the word "crushed". If the crushed pineapple, when drained by the method specified in paragraph (b) (2) (i) of this section, yields not less than 73 percent but less than 78 percent by weight of drained material, the word "crushed" or the words "crushed pineapple" in the name of the food may be preceded or followed by the words "heavy pack", and if it yields 78 percent or more by weight of drained material the word "crushed" or the words "crushed pineapple" may be preceded or followed by the words "solid pack".

(7) (i) The labels of canned pineapple prepared from the optional forms of pineapple specified in paragraph (a) (1) (i) to (vii), inclusive, of this section shall bear the name of the optional packing medium used as specified in paragraph (a) (2) of this section, preceded by "in" or "packed in". Whenever the optional packing medium pineapple juice, as specified in paragraph (a) (2) (ii) of this section, is used, the words "pineapple juice" may be preceded by the word "unsweetened". The labels of crushed pineapple canned with the optional packing media specified in paragraph (a) (2) (ii) to (vi), inclusive, of this section shall bear the statement "in _____" or "packed in _____", the blank being filled in with the name of the optional packing medium used as specified in paragraph (a) (2) of this section, but in lieu of such statement crushed pineapple canned with pineapple juice (paragraph (a) (2) (ii) of this section) may be labeled "unsweetened", and crushed pineapple canned with pineapple juice and sugar may be labeled "lightly sweetened" or "heavily sweetened" or "extra heavily sweetened", if the drained liquid conforms to the density ranges specified in paragraph (a) (3) of this section for light sirup, heavy sirup, or extra heavy sirup, respectively.

(ii) When any optional ingredient permitted by one of the following specified in paragraph (a) (5) of this section is used, the label shall bear the words set forth below after the number of such subparagraph:

(*a*) "Spiced" or "spice added" or "with added spice" or, in lieu of the word "spice", the common name of the spice.

(*b*) "Flavoring added" or "with added flavoring" or, in lieu of the word "flavoring", the common name of the flavoring.

(*c*) "Seasoned with vinegar" or "seasoned with _____ vinegar", the blank being filled in with the name of the vinegar used.

When two or all of the optional seasoning ingredients specified in paragraph (a) (5) (i), (ii) and (iii) of this section are used, such words may be combined, as for example, "seasoned with vinegar, cloves, and cinnamon oil".

(ii) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements herein specified, showing the optional ingredients used, shall conspicu-

ously precede or follow the name, without intervening written, printed, or graphic matter, except that the adjectival designation of the State, Territory, or possession of the United States or of the foreign country in which the pineapples were grown may intervene.

(b) *Quality*—(1) The standard of quality for canned pineapple is as follows:

(i) In the case of broken slices, not more than 10 percent of the drained weight may consist of pieces having an arc of less than 90° and not more than 5 percent of the drained weight of the contents of the container, as determined by the method prescribed in paragraph (b)(2)(i) of this section:

(*a*) Consists of pieces that measure in thickness less than 5/16 inch or more than 1 inch; or

(*b*) Consists of pieces that measure less than ¾ inch in width as measured from the outer edge to the inner edge.

(ii) (*a*) In the case of cubes or diced pineapple, not more than 10 percent of the drained weight consists of units of such size that they pass through the screen when tested by the method prescribed in paragraph (b)(2)(iv) of this section; and

(*b*) Not more than 15 percent of the drained weight consists of pieces weighing more than 3/32 ounce each.

(iii) In the case of chunks, not more than 15 percent of the drained weight consists of pieces weighing less than 3/16 ounce each.

(iv)(*a*) In the case of slices and spears, the drained weight of the largest unit in the container is not more than 1.4 times the weight of the smallest.

(*b*) In the case of half slices, the drained weight of the largest unit in the container is not more than 1.75 times the weight of the smallest (except for an occasional broken piece due to splitting or an occasional whole slice not quite completely cut through).

(v) In the case of broken slices, not more than 5 percent of the drained weight of the contents of the can consists of broken slices having an outside diameter differing by as much as ⅜-inch from that of those present in greatest proportion by weight.

(vi) In the case of tidbits, not more than 15 percent of the drained weight consists of tidbits each of which weighs less than three-fourths as much as the average weight of all the untrimmed tidbits in the container.

(vii) In the case of slices and half slices, not more than 7½ percent by count of the units in a container may be excessively trimmed, but in any container having not more than 10 units, one unit may be excessively trimmed, and in any container having more than 10 units, but not more than 27 units, two units may be excessively trimmed. Such slices and half slices are excessively trimmed if the portion trimmed away exceeds 5 percent of the apparent physical bulk of the perfectly formed unit and if such trimming destroys the normal circular shape of the outer or inner edge of the unit.

(viii) In the case of broken slices and spears, not more than 15 percent by count of the total units in the container, and, in the case of tidbits, not more than 15 percent of the drained weight, consist of units excessively trimmed. Broken slices, spears, and tidbits are excessively trimmed if the normal shape of these units is destroyed by such trimming.

(ix) In the case of slices, half slices, broken slices, spears, chunks, cubes, and tidbits, not more than 12½ percent by count of the units in any container may be blemished, but in containers having not more than five units, one unit may be blemished; in containers having more than five units but not more than 10 units, two units may be blemished; and in containers having more than 10 units, but not more than 32 units, four units may be blemished. Blemishes include:

(*a*) Any of the following, if in excess of 1/16 inch in the longest dimension on the exposed surface of the unit: Eyes, pieces of shell, brown spots.

(*b*) Deep fruit eyes.

(*c*) Bruised portions.

(*d*) Other abnormalities that it is possible to detect in good commercial practice before sealing in the containers.

(x) In the case of crushed pineapple, not more than 1¼ percent of the drained weight of the contents of the can consists of fragments bearing such blemishes.

(xi) In the case of spears, not more than one unit per container is mashed; in the case of slices and half slices, not more than one unit in containers of 25 units or less, and not more than three units in containers of more than 25 units are mashed; in the case of broken slices, not more than 5 percent by count of the units in the container is mashed; in the case of chunks, not more than three of the units in containers of less than 70 units, or 5 percent of the units in containers of 70 units or more, is mashed; in the case of tidbits, not more than three of the units in containers of less than 150 units, or 2 percent of the units in containers of 150 units or more, is mashed. (A unit that has lost its normal shape because of ripeness and which bears no mark of mechanical injury shall not be considered as mashed.)

(xii) In the case of all forms of canned pineapple, not more than 1.1 ounces of core is contained in 1 pound of drained fruit, as determined by the method prescribed in paragraph (b)(2)(viii) of this section.

(xiii) In the case of all forms of canned pineapple, not more than 1.35 grams of acid, as determined by the method prescribed in paragraph (b)(2)(ix) of this section and calculated as anhydrous citric acid, is contained in 100 milliliters of the liquid drained from the product 15 days or more after the pineapple is canned.

(xiv) In the case of crushed pineapple the drained weight of pineapple, as determined by the method prescribed in paragraph (b)(2)(i) of this section, is not less than 63 percent of the net weight of the contents of the container.

(2) The methods to be employed to determine whether canned pineapple meets the requirements of paragraph (b)(1) of this section are as follows:

(i) Determine the drained weight of the canned pineapple by the following procedure: Pour the contents of the can on a round sieve made with No. 8 woven-wire cloth complying with the specifications for such cloth in Table I of "Standard Specifications for Sieves," published March 1, 1940, in L.C. 584 of the United States Department of Commerce, National Bureau of Standards. Use a sieve 8 inches in diameter for containers of less than 3 pounds net contents and a sieve 12 inches in diameter for larger containers. Incline the sieve, without shifting the contents, to facilitate draining. Allow to drain for 2 minutes from the time the contents of the container are poured on the sieve. Immediately transfer the drained pineapple to a clean dry, tared pan by inverting the sieve over the pan in one moderately rapid motion, and determine the weight of the drained pineapple.

(ii) In the case of broken slices and spears, check the dimensions and weight of each unit against the requirements of paragraph (b)(1)(i), (iv), and (v) of this section.

(iii) In the case of cubes, chunks, and tidbits, check the weight of the units against the requirements of paragraph (b)(1)(ii)(*b*), (iii), and (vi) of this section.

(iv) Test cubes for compliance with paragraph (b)(1)(ii)(*a*) of this section by placing the cubes, a few at a time, on the meshes of a sieve designated as 5/16 inch in Table I of "Standard Specifications for Sieves," described in paragraph (b)(2)(i) of this section. After shaking gently, remove those that remain on the sieve before testing the next portion. Continue portionwise until all units are tested, then determine the aggregate weight of those units that have passed through the sieve.

(v) Except in the case of cubes, chunks, and crushed pineapple, inspect all the units in the container to determine those that have been excessively trimmed, as defined in paragraph (b)(1)(vii) or (viii) of this section.

(vi) Except in the case of crushed pineapple, segregate and count each unit that is blemished as defined in paragraph (b)(1)(ix) of this section. In the case of crushed pineapple, segregate each fragment of crushed pineapple bearing a blemish and determine the aggregate weight of such fragments to determine compliance with paragraph (b)(1)(x) of this section.

(vii) Except in the case of cubes and crushed pineapple, count the total units in the container and the number of mashed units, to determine compliance with paragraph (b)(1)(xi) of this section.

(viii) In the case of each form of optional pineapple ingredient, identify and separate any core material cleanly from each of the units in the container, and weigh the aggregate of such core material. Calculate the weight of the core

material per pound of drained fruit, to determine compliance with paragraph (b)(1)(xii) of this section.

(ix) Determine the total acidity of the drained liquid by titration, using the following method: Measure with a pipette 10 milliliters of the unfiltered drained liquid into a 250-milliliter Erlenmeyer flask. Add 25 milliliters of freshly boiled, distilled water and 0.3 milliliter of 1-percent phenolphthalein solution. Titrate with one-tenth normal sodium hydroxide solution to a faint, permanently pink coloration. Multiply the number of milliliters of one-tenth normal sodium hydroxide required by 0.064 to calcuate the number of grams of anhydrous citric acid per 100 milliliters of drained liquid.

(3) If the quality of canned pineapple falls below the standards prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in § 130.14(a) of this subchapter, in the manner and form therein specified. However, if the quality of canned pineapple falls below standard with respect to only one of the factors of quality specified in paragraph (b)(1)(i) through (xiv) of this section, there may be substituted for the second line of such general statement of substandard quality a new line as specified below, after the number corresponding to each subparagraph of paragraph (b)(1) of this section that such canned pineapple fails to meet as follows:

(i) "Small broken pieces" or "Thick broken pieces", as the case may be.
(ii)(*a*) "Irregular small pieces";
(*b*) "Mixed sizes". (These words are to be used only where the cubes are of mixed sizes and the tolerance for units larger than maximum size is exceeded.)
(iii) "Irregular small pieces".
(iv) "Mixed sizes".
(v) "Mixed sizes".
(vi) "Mixed sizes".
(vii) "Excessively trimmed".
(viii) "Excessively trimmed".
(ix) "Blemished" or "Contains blemished pieces".
(x) "Blemished" or "Contains blemished pieces".
(xi) "Mashed units" or "Contains mashed units".
(xii) "Poorly cored" or "Excessive core".
(xiii) "Excessively tart".
(xiv) "Contains excess liquid".

(c) *Fill of Container*—(1) The standard of fill of container for canned crushed pineapple is a fill of not less than 90 percent of the total capacity of the container, as determined by the general method for fill of container prescribed in § 130.12(b) of this chapter.

(2) If canned crushed pineapple falls below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

§ 145.181 Artificially sweetened canned pineapple.

(a) Artificially sweetened canned pineapple is the food that conforms to the definition and standard of identity prescribed for canned pineapple by § 145.180(a), except that in lieu of a packing medium specified in § 145.180(a)(2), the packing medium used is water artificially sweetened with saccharin, sodium saccharin, or a combination of both. Such packing medium may be thickened with pectin.

(b)(1) The specified name of the food is "artificially sweetened _____", the blank being filled in with the name prescribed by § 145.180(a) for canned pineapple having the same optional pineapple ingredient.

(2) The artificially sweetened food is subject to the requirements for label statement of optional ingredients used, as prescribed for canned pineapple by § 145.180(a). If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin".

§ 145.185 Canned plums.

(a) *Identity*—(1) *Ingredients.* Canned plums is the food prepared from clean, sound, and mature fruit of plum varieties conforming to the characteristics of *Prunus domestica* L., greengage varieties conforming to the characteristics of *Prunus italica* L., mirabelle or damson varieties conforming to the characteristics of *Prunus insititia* L., or cherry varieties conforming to the characteristics of *Prunus cerasifera* Ehrh. The food consists of one of the optional styles of the plum ingredient, specified in paragraph (a)(2) of this section, and one of the optional packing media specified in paragraph (a)(3) of this section. Such food may also contain one, or any combination of two or more of the following safe and suitable optional ingredients:

(i) Natural and artificial flavors.
(ii) Spice.
(iii) Vinegar, lemon juice, or organic acids.
(iv) Artificial coloring.

Such food is sealed in a container and before or after sealing is so processed by heat so as to prevent spoilage.

(2) *Optional styles of the plum ingredient.* The optional plum ingredients specified in paragraph (a)(1) of this section are peeled or unpeeled:

(i) Whole.
(ii) Halves.

Peeled or unpeeled whole plums are pitted or, alternatively, unpitted. Peeled or unpeeled plum halves are pitted.

(3) *Packing media*—(i) The optional packing media referred to in paragraph (a)(1) of this section, as defined in § 145.3 are:

(*a*) Water.
(*b*) Fruit juice(s) and water.
(*c*) Fruit juice(s).

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in § 145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in Part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in § 145.3.

(ii) When a sweetener is added as a part of any such liquid packing medium, the density range of the resulting packing medium expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure prescribed in § 145.3(m) shall be designated by the appropriate name for the respective density ranges, namely:

(*a*) When the density of the solution is 11 percent or more but less than 15 percent, the medium shall be designated as "slightly sweetened water", or "extra light sirup", "slightly sweetened fruit juice(s) and water" or "slightly sweetened fruit juice(s)", as the case may be.

(*b*) When the density of the solution is 15 percent or more, but less than 19 percent, the medium shall be designated as "light sirup", "lightly sweetened fruit juice(s) and water", or "lightly sweetened fruit juice(s)", as the case may be.

(*c*) When the density of the solution is 19 percent or more, but less than 25 percent, the medium shall be designated as "heavy sirup", "heavily sweetened fruit juice(s) and water", or "heavily sweetened fruit juice(s)", as the case may be.

(*d*) When the density of the solution is 25 percent or more, but less than 35 percent, the medium shall be designated as "extra heavy sirup", "extra heavily sweetened fruit juice(s) and water", or "extra heavily sweetened fruit juice(s)", as the case may be.

(4) *Labeling requirements*—(i) The name of the food is "plums" accompanied by the color designation "yellow" or "golden" or "red" or "purple", as appropriate, or the specific name of the variety or "Greengage plums", "Damson plums", "Cherry plums", "Mirabelle plums". The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, "Spice added", or in lieu of the word "Spice", the common name of the spice; "Seasoned with vinegar". When two or more of the optional ingredients specified in paragraph (a)(1)(ii) and (iii) of this section are used, such words may be combined as for example, "Seasoned with cider vinegar, cloves, and cinnamon oil".

(ii) The style of the plum ingredient as provided in paragraph (a)(2) of this section and the name of the packing medium specified in paragraph (a)(3)(i) and (ii) of this section, preceded by "In" or "Packed in" shall be included as part of the name or in close proximity to the name of the food. The style of the plum ingredient shall be preceded or followed by "Peeled" when the plums are peeled and by "Pitted" in the case of whole pitted plums. "Halves" may be alternatively designated "Halved". When the packing medium is prepared with a sweetener(s) which imparts a taste, flavor or other characteristics to the finished food in addition to sweetness, the name of the packing medium shall be

accompanied by the name of such sweetener(s), as for example, in the case of a mixture of brown sugar and honey, an appropriate statement would be "_____ sirup of brown sugar and honey", the blank to be filled in with the word "light", "heavy", or "extra heavy", as the case may be. When the liquid portion of the packing media provided for in paragraph (a)(3) (i) and (ii) of this section consists of fruit juice(s), such juice(s) shall be designated in the name of the packing medium as:

(*a*) In the case of a single fruit juice, the name of the juice shall be used in lieu of the word "fruit",

(*b*) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word "fruit" in the name of the packing medium, or be declared on the label as specified in paragraph (a)(4)(iii) of this section, and

(*c*) In the case of a single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words "from concentrate(s)" shall follow the word "juice(s)" in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (a)(4)(iii) of this section.

(iii) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (a)(4)(ii)(*b*) of this section, such names and the words "from concentrate", as specified in paragraph (a)(4)(ii)(*c*) of this section, shall appear in an ingredient statement pursuant to the requirements of § 101.3(d) of this chapter.

(iv) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(b) *Quality*—(1) The standard of quality for canned plums is as follows:

(i) *Blemishes (damaged)*. After draining in accordance with the procedure set out in § 145.3(n) not more than 30 percent by weight of the drained plums consists of plums which have been blemished or damaged by any of the following factors either singly or in combination: Damaged by insects; appearance or eating quality materially affected by friction, disease, external stone gum or discoloration.

(ii) *Crushed or broken units in whole and halves styles*. In the case of the whole styles, not more than 25 percent by weight of the drained plums are deformed or broken to an extent that the normal shape of the fruit is seriously affected. In the case of the halves style, not more than 25 percent by weight of the drained plums are damaged or torn to such an extent that they are smaller than 50 percent of a plum half.

(iii) *Blemishes and crushed or broken units*. Not more than 35 percent by weight of the drained plums consist of both blemishes as specified in paragraph (b)(1)(i) of this section and crushed or broken units in the case of the whole and halves styles as specified in paragraph (b)(2)(ii) of this section.

(iv) *Extraneous plant material*. Not more than one piece of stalk or stem from the plum tree or other harmless extraneous plant material per 200 grams (7 ounces) of drained plums.

(v) *Loose pits in whole style*. Not more than three loose pits per 500 grams (17.6 ounces) of drained plums.

(vi) *Pits or pieces of pits in whole pitted and halves styles*. Not more than two pits or pieces of pits per 500 grams (17.8 ounces) of drained plums.

(2) Determine compliance as specified in § 145.3(o) except that a lot shall be deemed to be in compliance for extraneous plant material, loose pits in whole style, and pits or pieces of pits in whole pitted and halves styles based on the average of all samples analyzed according to the sampling plans set out in § 145.3(p).

(3) If the quality of canned plums falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in § 130.14(a) of this chapter, in the manner and form therein specified; however, if the quality of the canned plums falls below standard with respect to only one of the factors of quality specified in paragraph (b)(1)(i) through (vi) of this section, there may be substituted for the second line of such general statement of substandard quality ("Good Food—Not High Grade") a new line, as specified after the corresponding designation of paragraph (b)(1) of this section which the canned plums fail to meet, as follows:

(i) "Blemished";

(ii) "Partly crushed or broken";

(iii) "Blemished and partly crushed or broken";

(iv) "Contains extraneous plant material";

(v) "Contains loose pits"; or

(vi) "Contains pits" or "Contains pieces of pits".

(c) *Fill of container*—(1) The standard of fill of container for canned plums is:

(i) The fill of the plums and packing medium, as determined by the general method for fill of container prescribed in § 130.12(b) of this chapter, is not less than 90 percent of the total capacity of the container.

(ii) The drained weight of the plum ingredient as determined by the method prescribed in § 145.3(n) is not less than 50 percent for whole styles and 55 percent for halves styles based on the water capacity of containers as determined in § 130.12(a) of this chapter.

(2) Determine compliance for fill of container as specified in § 145.3(o).

(3) If canned plums fall below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified. If canned plums fall below the standard of fill of container in respect to drained weight, the words "Low drained weight" shall follow the general statement of substandard fill on the label.

§ 145.190 Canned prunes.

(a) *Ingredients*. Canned prunes is the food prepared from dried prunes, which may be packed as a solid pack or in one of the optional packing media specified in paragraph (b) of this section. Such food may also contain one, or any combination of two or more, of the following safe and suitable optional ingredients:

(1) Natural and artificial flavors.

(2) Spice.

(3) Vinegar, lemon juice, or organic acids.

(4) Unpeeled pieces of citrus fruits.

Such food is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

(b) *Packing media*—(1) The optional packing media referred to in paragraph (a) of this section, as defined in § 145.3 are:

(i) Water.

(ii) Fruit juice(s) and water.

(iii) Fruit juice(s).

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in § 145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in Part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in § 145.3.

(2) When a sweetener is added as a part of any such liquid packing medium, the density range of the resulting packing medium expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure prescribed in § 145.3(m) shall be designated by the appropriate name for the respective density ranges, namely:

(i) When the density of the solution is less than 20 percent, the medium shall be designated as "slightly sweetened water"; or "extra light sirup"; "slightly sweetened fruit juice(s) and water"; or "slightly sweetened fruit juice(s)", as the case may be.

(ii) When the density of the solution is 20 percent or more but less than 24 percent, the medium shall be designated as "light sirup"; "lightly sweetened fruit juice(s) and water"; or "lightly sweetened fruit juice(s)", as the case may be.

(iii) When the density of the solution is 24 percent or more but less than 30 percent, the medium shall be designated as "heavy sirup"; "heavily sweetened fruit juice(s) and water"; or "heavily sweetened fruit juice(s)", as the case may be.

(iv) When the density of the solution is 30 percent or more but not more than 45 percent, the medium shall be designated as "extra heavy sirup"; "extra heavily sweetened fruit juice(s) and water"; or "extra heavily sweetened fruit juice(s)", as the case may be.

(c) *Labeling requirements*—(1) The name of the food is "prunes—prepared from dried prunes". The words "prepared from dried prunes" shall be in close proximity to the word "prunes" and shall be of the same style and not less than ½ of the point size of the type used for the

word "prunes". The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, "Spice added", or in lieu of the word "Spice", the common name of the spice, "Seasoned with vinegar" or "Seasoned with unpeeled pieces of citrus fruit". When two or more of the optional ingredients specified in paragraph (a) (2) through (4) of this section are used, such words may be combined as for example, "Seasoned with cider vinegar, cloves, cinnamon oil and unpeeled pieces of citrus fruit."

(2) When the food is prepared with a packing medium, the name of the packing medium specified in paragraph (b) (1) and (2) of this section, preceded by "In" or "Packed in" and the words "cooked", "stewed", or "prepared", shall be included as part of the name or in close proximity to the name of the food. When no packing medium is used, the words "solid pack" or "moist pack" or the word "moistened" followed by the words "without sirup" shall be included as part of the name or in close proximity to the name of the food. When the packing medium is prepared with a sweetener(s) which imparts a taste, flavor or other characteristic to the finished food in addition to sweetness, the name of the packing medium shall be accompanied by the name of such sweetener(s), as for example in the case of a mixture of brown sugar and honey, an appropriate statement would be "_____ sirup of brown sugar and honey", the blank to be filled in with the word "light", "heavy", or "extra heavy" as the case may be. When the liquid portion of the packing media provided for in paragraph (b) (1) and (2) of this section consists of fruit juice(s), such juice(s) shall be designated in the name of the packing medium as:

(i) In the case of a single fruit juice, the name of the juice shall be used in lieu of the word "fruit",

(ii) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word "fruit" in the name of the packing medium, or be declared on the label as specified in paragraph (c) (3) of this section, and

(iii) In the case of the single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words "from concentrate(s)" shall follow the word "juice(s)" in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (c) (3) of this section.

(3) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (c) (2) (ii) of this section, such names and the words "from concentrate", as specified in paragraph (c) (2) (iii) of this section, shall appear in an ingredient statement pursuant to the requirements of § 101.3(d) of this chapter.

(4) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

PART 146—CANNED FRUIT JUICES

Subpart A—General Provisions

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146.166 Concentrate for orange flavored drink.
146.167 Powdered orange flavored drink.
146.168 Water-extracted soluble orange solids.
146.169 Dehydrated water-extracted soluble orange solids.
146.170 Comminuted oranges.
146.171 Dehydrated comminuted oranges.
146.172 Extract of comminuted oranges.
146.175 Dehydrated extract of comminuted oranges.
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146.177 Dehydrated juicy orange pulp for manufacturing.
146.185 Canned pineapple juice.
146.187 Canned prune juice.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046 as amended, 1055–1056 as amended (21 U.S.C. 341, 371).

Subpart A—General Provisions

§ 146.3 Definitions.

For the purposes of this part:

(a) The term "corn sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of cornstarch, and includes dried corn sirup. The solids of corn sirup and of dried corn sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose.

(b) The term "dextrose" means the hydrated or anhydrous, refined monosaccharide obtained from hydrolyzed starch.

(c) The term "dried glucose sirup" means the product obtained by drying glucose sirup.

(d) The term "glucose sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of glucose sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose.

(e) The term "invert sugar sirup" means an aqueous solution of inverted or partly inverted, refined or partly refined sucrose, the solids of which contain not more than 0.3 percent by weight of ash, and which is colorless, odorless, and flavorless, except for sweetness.

(f) The term "sugar" means refined sucrose.

(g) Compliance means the following: Unless otherwise provided in a standard, a lot of canned fruits shall be deemed in compliance for the following factors, to be determined by the sampling and acceptance procedure as provided in paragraph (h) of this section, namely:

(1) *Quality.* The quality of a lot shall be considered acceptable when the number of defectives does not exceed the acceptance number in the sampling plans.

(2) *Fill of container.* A lot shall be deemed to be in compliance for fill of container when the number of defectives does not exceed the acceptance number (c) in the sampling plans.

(h) The sampling and acceptance procedure means the following:

(1) *Definitions*—(i) *Lot.* A collection of primary containers or units of the same size, type, and style manufactured or packed under similar conditions and handled as a single unit of trade.

(ii) *Lot size.* The number of primary containers or units in the lot.

(iii) *Sample size.* The total number of sample units drawn for examination from a lot.

(iv) *Sample unit.* A container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for the examination or testing as a single unit.

(v) *Defective.* Any sample unit shall be regarded as defective when the sample unit does not meet the criteria set forth in the standards.

(vi) *Acceptance number (c).* The maximum number of defective sample units permitted in the sample in order to consider the lot as meeting the specified requirements.

(vii) *Acceptable quality level (AQL).* The maximum percent of defective sample units permitted in a lot that will be accepted approximately 95 percent of the time.

(2) *Sampling plans:*

Lot size (primary containers)	Size of container	
	Net weight equal to or less than 1 kg (2.2 lb)	
	n	c
4,800 or less	13	2
4,801 to 24,000	21	3
24,001 to 48,000	29	4
48,001 to 84,000	48	6
84,001 to 144,000	84	9
144,001 to 240,000	126	13
Over 240,000	200	19
	Net weight greater than 1 kg (2.2 lb) but not more than 4.5 kg (10 lb)	
	n	c
2,400 or less	13	2
2,401 to 15,000	21	3
15,001 to 24,000	29	4
24,001 to 42,000	48	6
42,001 to 72,000	84	9
72,001 to 120,000	126	13
Over 120,000	200	19
	Net weight greater than 4.5 kg (10 lb)	
	n	c
600 or less	13	2
601 to 2,000	21	3
2,001 to 7,200	29	4
7,201 to 15,000	48	6
15,001 to 24,000	84	9
24,001 to 42,000	126	13
Over 42,000	200	19

n=number of primary containers in sample.
c=acceptance number.

Subpart B—Requirements for Specific Standardized Canned Fruit Juices and Beverages

§ 146.110 Cranberry juice cocktail.

(a) Cranberry juice cocktail—a juice drink is the beverage food prepared from one or both of the cranberry juice ingredients specified in paragraph (b) of this section to which water and one or more safe and suitable nutritive sweeteners are added. The finished food is filtered and contains not less than 25 percent by volume of equivalent single strength cranberry juice. The soluble solids content of the finished food is not less than 14° Brix nor more than 16° Brix, as determined by refractometer. It may contain added vitamin C in a quantity prescribed by paragraph (c) of this section. The acid content of the food, calculated as anhydrous citric acid, is not less than 0.55 gram per 100 milliliters. The food is sealed in a container and so processed by heat, before or after sealing, as to prevent spoilage.

(b) The cranberry juice ingredients referred to in paragraph (a) of this section are cranberry juice and concentrated cranberry juice. For the purpose of this section cranberry juice is the juice extracted from mature, well colored, sound, washed cranberries and concentrated cranberry juice is cranberry juice from which part of the water has been removed.

(c) Vitamin C may be added in a quantity such that the total vitamin C in each 6 fluid ounces of the finished food amounts to not less than 30 milligrams and not more than 60 milligrams.

(d) The name of the food is "Cranberry juice cocktail—a juice drink—contains not less than 25 percent cranberry juice". The words "a juice drink" shall appear on the label either on the same line with or centered on a line immediately below the words "cranberry juice cocktail". The words "contains not less than 25 percent cranberry juice" shall appear on a line immediately below and be centered with the line preceding it. The words "a juice drink—contains not less than 25 percent cranberry juice" shall be in letters not less than one-half the height of the largest letter in the words "cranberry juice cocktail".

(e) (1) The label shall name the sweetening ingredients used. When vitamin C is added, as provided for by paragraph (c), it shall be designated on the label as "vitamin C added" or "with added vitamin C". The label shall conform to the labeling requirements prescribed for foods which purport to be or are represented for special dietary uses by regulations promulgated pursuant to section 403(j) of the Federal Food, Drug, and Cosmetic Act.

(2) Statements of the ingredients present as specified in this paragraph shall be set forth on the label with such prominence and conspicuousness as to render them likely to be read by the ordinary individual under customary conditions of purchase.

NOTE.—§ 146.110 (formerly § 27.127) was stayed in its entirety at 33 F.R. 10088, July 13, 1968.

§ 146.111 Artificially sweetened cranberry juice cocktail.

(a) Artificially sweetened cranberry juice cocktail—a juice drink is the food that conforms to the definition and standard of identity prescribed for cranberry juice cocktail—a juice drink by § 146.110, except that in lieu of nutritive sweeteners it is sweetened with one or more of the artificial sweeteners listed in and complying with Parts 170 through 189 of this chapter, and the soluble solids specifications prescribed in § 146.110(a) do not apply. The quantity of artificial sweeteners added is sufficient to sweeten the beverage to the same sweetness taste level as that of the food conforming to § 146.110.

(b) The name of the food is "Artificially sweetened cranberry juice cocktail—a juice drink—contains not less than 25 percent cranberry juice". The words "artificially sweetened" shall be of the same size and style of type as the words "cranberry juice cocktail" and the words "a juice drink—contains not less than 25 percent cranberry juice" shall be of the same size and placement as prescribed in § 146.110(d).

(c) The food is subject to the requirements for label statement of ingredients as prescribed for cranberry juice cocktail—a juice drink by § 146.110 and is labeled to conform to the labeling requirements prescribed for foods which purport to be or are represented for special dietary uses by regulations promulgated pursuant to section 403(j) of the Federal Food, Drug, and Cosmetic Act.

NOTE.—§ 146.111 (formerly § 27.128) was stayed in its entirety at 33 F.R. 10088, July 13, 1968.

§ 146.113 Canned fruit nectars.

(a) Canned fruit nectars are the pulpy, liquid foods prepared from one or more of the optional fruit ingredients specified in paragraph (b) of this section in an amount not less than the percentage specified in that paragraph, water, and one or more of the optional sweetening ingredients as provided for in paragraph (d) of this section. They may contain one or more of the optional ingredients as provided for in paragraph (e) of this section. The consistency of the finished product is such that the time of flow is not less than 30 seconds when tested by the method set forth in "Consistency Measurement of Fruit Nectars and Fruit Juice Products," published in the "Journal of the Association of Official Agricultural Chemists," p. 411, vol. 42, 1959. Such food is sealed in a container and so processed by heat, either before or after sealing, as to prevent spoilage.

(b) (1) The optional fruit ingredients referred to in paragraph (a) of this section are fruit puree, pulp, juice, or concentrates thereof, as prepared from whole, mature fruits of the following varieties: Apple, apricot, blackberry, boysenberry, cherry guava, loganberry, mango, nectarine, papaya, passion fruit, peach, pear, pineapple, and plum. Apples, cherries, passion fruit, and pineapples are used only in combination with one or more of the other fruits listed.

(2) The fruit ingredients contain finely divided insoluble fruit solids but do not contain seeds, pits, or other coarse or hard substances capable of being avoided by good canning practices.

(3) Single-fruit nectars are made from fruits of a single variety. The proportion of fruit ingredient used on an equivalent single strength basis is not less than 40 percent by weight of the finished food; except that for apricot nectar it is not less than 35 percent, for papaya nectar it is not less than 33⅓ percent, and for guava nectar it is not less than 25 percent. Multiple-fruit nectars are made from two or more varieties of fruit, and they may be made by blending single-fruit nectars provided that each single-fruit nectar used meets its fruit ingredient requirement. The fruit ingredient requirements for those fruits that by paragraph (b)(1) of this section are restricted for use in combination with other fruits are: Apples—not less than 40 percent, cherries—not less than 40 percent, passion fruit—not less than 15 percent, and pineapples—not less than 40 percent. Each multiple-fruit nectar made by any procedure other than by the method of blending single-fruit nectars shall contain no less of each fruit ingredient than it would be required to have if made by the blending method. In no case shall the quantity of a fruit ingredient be less than that required to impart a definite flavor or other definite characteristic to the nectar. The weight of any fruit ingredient shall be determined as follows: Determine the percent of soluble solids in such fruit ingredient by the method prescribed in section 29.011 of "Official Methods of Analysis

of the Association of Official Agricultural Chemists," 10th Edition, 1965, page 487, under "Solids." Use this method notwithstanding the presence of insoluble solids. Multiply the result so found by the weight of each fruit ingredient used and divide the product by the Brix value for each such fruit ingredient set forth in paragraph (c)(3) of this section. The result is the equivalent weight of the individual single strength fruit ingredients. For example, 1,180 pounds of concentrated peach ingredient having 30 percent soluble solids is used. The equivalent weight of single strength peach ingredient would be:

(1,180×30÷11.8=3,000 pounds.)

(c) Any requirement of this section with respect to the weight of any fruit means:

(1) In the case of fruit the proper preparation of which involves the removal of pits, seeds, skins, cores, or other parts, the weight of such fruit exclusive of all such substances removed therefrom; and

(2) The weight of the fruit exclusive of the weight of water or any other substance added for any processing, packing, or canning of such fruit, or otherwise added to such fruit.

(3) For the purposes of this section the weight of any fruit ingredient shall be converted to the equivalent weight of single strength fruit ingredient having a Brix value as follows:

Name of fruit:	Brix value
Apple	13.3
Apricot	14.3
Blackberry	10.0
Boysenberry	10.0
Cherry	14.3
Guava	7.7
Loganberry	10.5
Mango	13.0
Nectarine	11.8
Papaya	11.5
Passion fruit	14.5
Peach	11.8
Pear	15.4
Pineapple	13.0
Plum	14.3

(d) The optional sweetening ingredients referred to in paragraph (a) of this section are: Sugar, invert sugar sirup, dextrose, corn sirup, dried corn sirup, glucose sirup, and dried glucose sirup.

(e) Optional ingredients that may be added in making fruit nectars are one or more of the following:

(1) Acidifiers: Lemon juice, concentrated lemon juice, citric acid, malic acid, and fumaric acid.

(2) Ascorbic acid as an antioxidant preservative in a quantity not to exceed 150 parts per million.

(3) Ascorbic acid (vitamin C) added in such quantity that the total ascorbic acid in each 4 fluid ounces of the finished fruit nectar amounts to not less than 30 milligrams and not more than 60 milligrams.

(f) The names of the fruit nectars for which standards of identity are prescribed by this section are:

(1) If the fruit ingredient is prepared from a single variety of fruit the name is "nectar" preceded by the name of the fruit; for example, "Apricot nectar".

(2) If the fruit ingredient is a combination of two or more fruits and the weight of each is not less than one-tenth of the weight of the combination, the name is "nectar" preceded by the names of the fruits arranged in descending order of predominance; for example, "Apricot and papaya nectar".

(3) If the fruit ingredient is a combination, the nectar shall be so named as to differentiate those fruits furnishing one-tenth or more to the weight of the combination from those fruits furnishing less than one-tenth to such weight. The names of those fruits furnishing one-tenth or more to the combination shall be shown as prescribed in paragraph (f)(2) of this section; or, alternatively, in the case of combinations wherein each of four or more fruits furnishes one-tenth or more to the weight of the combination, their names may be listed in descending order of predominance immediately following the words "Blended fruit nectar". The names of any fruits furnishing less than one-tenth of the weight of the combination shall be shown immediately following the rest of the name of the nectar by listing them in the blank of the statement "with added_____" or "_____ added". For example, nectar made with a combination containing: 35 percent pear, 25 percent peach, 20 percent plum, 15 percent apricot, and 5 percent passion fruit may be named "Pear, peach, plum, apricot nectar, passion fruit added", or alternatively, it may be named "Blended fruit nectar—pear, peach, plum, apricot, with added passion fruit".

(g) The common names of optional ingredients used shall be shown on the principal display panel or panels of the label with such prominence and conspicuousness that they are likely to be read and understood by ordinary individuals under customary conditions of purchase. The term "sweetener added" may be used in lieu of the name or names of the sweetening ingredient. When ascorbic acid is added as provided for in paragraph (e)(2) of this section, it shall be declared on the label by the statement "ascorbic acid added_____", the blank being filled in with "to preserve color and flavor" or "as a preservative". A fruit nectar containing ascorbic acid (vitamin C) as provided for in paragraph (e)(3) of this section shall bear on the label, in addition to the preservative declaration required by this paragraph, the statement "vitamin C added" or "with added vitamin C" and such statement shall be accompanied by labeling conforming to the requirements prescribed in the regulations established pursuant to section 403(j) of the Federal Food, Drug, and Cosmetic Act.

NOTE.—§ 146.113 (formerly § 27.126) was stayed in its entirety at 33 FR 10713, July 27, 1968.

§ 146.115 Lemonade.

(a) Lemonade is the beverage food prepared from one or more of the lemon juice ingredients specified in paragraph (b) of this section, water, and one or more of the optional sweetening ingredients specified in paragraph (c) of this section. It may contain one or more of the optional ingredients provided for in paragraph (d) of this section. The proportion of lemon juice ingredients used is sufficient to yield an acidity, calculated as anhydrous citric acid, of not less than 0.70 gram per 100 milliliters of the finished lemonade. The pulp content of lemonade may be adjusted by removing or by adding lemon pulp in accordance with good manufacturing practice. The beverage made by diluting frozen concentrate for lemonade, identified in § 146.120, with water to meet the requirements of this section is deemed to be lemonade. Lemonade may be treated with heat to reduce the enzymatic activity and the number of viable microorganisms. It may be preserved by refrigeration, by freezing, by the addition of preservatives as provided for in paragraph (d)(2) of this section, or by sealing in containers and so processing by heat, either before or after sealing, as to prevent spoilage.

(b) The lemon juice ingredients referred to in paragraph (a) of this section are lemon juice and concentrated lemon juice, either of which may be frozen. For the purposes of this section, lemon juice is the juice expressed from mature lemons of an acid variety. Concentrated lemon juice is lemon juice from which part of the water has been removed. Lemon juice ingredients may be treated by heat to reduce the enzymatic activity and the number of viable microorganisms.

(c) The optional sweetening ingredients referred to in paragraph (a) of this section are: Sugar, invert sugar sirup, dextrose, corn sirup, dried corn sirup, glucose sirup, and dried glucose sirup.

(d) Optional ingredients that may be added in making lemonade are one or more of the following:

(1) Lemon oil, cold-pressed lemon oil, concentrated lemon oil, and lemon essence recovered during the concentration of lemon juice.

(2) The chemical preservatives: Sodium benzoate and sorbic acid.

(3) Safe and suitable buffering salts, emulsifying agents and weighting oils (emulsifying agents and weighting oils may be used only when an oil as provided for by paragraph (d)(1) of this section is added and in a quantity not greater than required to facilitate dispersion of such oil). Such ingredients are deemed safe if they are not food additives as defined by section 201(s) of the Federal Food, Drug, and Cosmetic Act, or if they are food additives as so defined, when they are used in conformity with regulations established pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act.

(e) The name of the food is "Lemonade". If the food is preserved by freezing, the name is "Frozen lemonade". If it is preserved by heat processing so as to prevent spoilage, the name is "Canned lemonade"; however, if it does not pur-

port to be a refrigerated or frozen product, the word "canned" may be omitted.

(f) The common names of optional ingredients used shall be shown on the principal display panel or panels of the label with such prominance and conspicuousness that they are likely to be read and understood by ordinary individuals under customary conditions of purchase. The term "sweetener added" may be used in lieu of the name or names of the sweetening ingredient. The term "flavor added" may be used in lieu of the names for lemon oil, cold-pressed lemon oil, concentrated lemon oil, or lemon essence. The name of the preservative ingredient used shall be accompanied by words to show that it is a preservative; for example, "preserved with sodium benzoate".

NOTE.—§ 146.115 (formerly § 27.99) was stayed in its entirety at 33 F.R. 10713, July 27, 1968.

§ 146.120 Frozen concentrate for lemonade.

(a) Frozen concentrate for lemonade is the frozen food prepared from one or both of the lemon juice ingredients specified in paragraph (b) of this section together with one or any mixture of safe and suitable nutritive carbohydrate sweeteners. The product contains not less than 48.0 percent by weight of soluble solids taken as the sucrose value determined by refractometer and corrected for acidity as given in "Correction of Refractometer Sucrose Readings for Citric Acid Content in Frozen Concentrate for Lemonade," by Yeatman, Senzel and Springer, "Journal of the Association of Analytical Chemists," vol. 59, p. 368 (1976).[3] When the product is diluted according to directions for making lemonade which shall appear on the label, the acidity of the lemonade, calculated as anhydrous citric acid, shall be not less than 0.70 gram per 100 milliliters, and the soluble solids, measured as described for the concentrate, shall be not less than 10.5 percent by weight.

(b) The lemon juice ingredients referred to in paragraph (a) of this section are:

(1) Lemon juice or frozen lemon juice or a mixture of these.

(2) Concentrated lemon juice or frozen concentrated lemon juice or a mixture of these.

For the purposes of this section, lemon juice is the undiluted juice expressed from mature lemons of an acid variety; and concentrated lemon juice is lemon juice from which part of the water has been removed. In the preparation of the lemon juice ingredients, the lemon oil content may be adjusted by the addition of lemon oil or concentrated lemon oil in accordance with good manufacturing practice, and the lemon pulp in the juice as expressed may be left in the juice or may be separated. Lemon pulp that has been separated, which may have been preserved by freezing, may be added in preparing frozen concentrate for lemonade, provided that the amount of pulp added does not raise the proportion of pulp in the finished food to a level in excess of that which would be present by using lemon juice ingredients from which pulp has not been separated. The lemon juice ingredients may be treated by heat, either before or after the other ingredients are added, to reduce the enzymatic activity and the number of viable microorganisms.

(c) Each of the ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 146.121 Frozen concentrate for artificially sweetened lemonade.

(a) Frozen concentrate for artificially sweetened lemonade conforms to the definition and standard of identity prescribed for frozen concentrate for lemonade by § 146.120, except that in lieu of nutritive sweeteners it is sweetened with one or more of the artificial sweetening ingredients listed in and complying with the requirements of Parts 172, 180 or 184 of this chapter, and the soluble solids specifications prescribed in § 146.120(a) do not apply. When the product is diluted according to directions which shall appear on the label, the acidity of the artificially sweetened lemonade, calculated as anhydrous citric acid, shall be not less than 0.70 gram per 100 milliliters. It may contain one or more safe and suitable dispersing ingredients serving the function of distributing the lemon oil throughout the food. It may also contain one or more safe and suitable thickening ingredients. Such dispersing and thickening ingredients are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act.

(b) [Reserved]

(c) The name of the food is "Frozen concentrate for artificially sweetened lemonade". The words "artificially sweetened" shall be of the same size and style of type as the word "lemonade".

(d) If an optional thickening or dispersing ingredient referred to in paragraph (a) of this section is used, the label shall bear the statement "_____ added" or "with added _____", the blank being filled in with the common name of the thickening or dispersing agent used. Such statement shall be set forth on the label with such prominence and conspicuousness as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase.

(e) Frozen concentrate for artificially sweetened lemonade is labeled to conform to the labeling requirements prescribed for foods which purport to be or are represented for special dietary use by regulations promulgated pursuant to section 403(j) of the act.

§ 146.125 Colored lemonade.

(a) Colored lemonade is the beverage food that conforms to the definition and standard of identity and is subject to the requirements for label statement of optional ingredients prescribed for lemonade by § 146.115, except that it is colored with a safe and suitable color. Such color is deemed safe if it is a color additive as defined in section 201(t) of the Federal Food, Drug, and Cosmetic Act and is used in conformity with regulations established pursuant to section 706 of the act. The beverage made by diluting frozen concentrate for colored lemonade, identified in § 146.126 with water to meet the requirements of this section is deemed to be colored lemonade.

(b) The name of the food conforms to the name prescribed by § 146.115, except that the word "lemonade" is immediately preceded by a word describing the color of the food; for example, "frozen pink lemonade".

(c) The authorized coloring ingredient used shall be shown on the label by the statement "_____ added" or "with added _____", the blank being filled in with words "artificial coloring" if the color additive used is artificial, or if it is not an artificial coloring the blank is filled in with the word "coloring" or with the common name of the color additive used; for example, "beet juice added".

NOTE.—§ 146.125 (formerly § 27.100) was stayed in its entirety at 33 FR 10713, July 27, 1968.

§ 146.126 Frozen concentrate for colored lemonade.

(a) Frozen concentrate for colored lemonade conforms to the definition and standard of identity prescribed for frozen concentrate for lemonade by § 146.120, except that it is colored with a safe and suitable fruit juice, vegetable juice, or any such juice in concentrated form, or with any other color additive ingredient suitable for use in food, including artificial coloring, used in conformity with regulations established pursuant to section 706 of the Federal Food, Drug, and Cosmetic Act.

(b) The name of the food is "Frozen concentrate for _____ lemonade", the blank being filled in with the word describing the color: for example, "Frozen concentrate for pink lemonade".

(c) Each of the ingredients specified in paragraph (a) of this section shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 146.130 Limeade.

Limeade is the beverage food that conforms to the compositional requirements prescribed by § 146.115 for lemonade, except that instead of using lemon juice ingredients, lemon pulp, and flavoring ingredients derived from lemons, the corresponding juice, pulp, and flavoring ingredients derived from mature limes of an acid variety are used. Limeade conforms to the labeling requirements prescribed by § 146.115 for lemonade, except that the name "limeade" replaces the name "lemonade".

NOTE.—§ 146.130 (formerly § 27.131) was stayed in its entirety at 33 FR 10713, July 27, 1968.

[3] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

§ 146.133 Canned pineapple-grapefruit juice drink.

(a) Canned pineapple-grapefruit juice drink is the beverage food prepared from one or both of the pineapple juice ingredients and one or both of the grapefruit juice ingredients specified in paragraph (b) of this section, water, and one or more of the optional sweetening ingredients specified in paragraph (c) of this section. It may contain one or more of the optional ingredients as provided for in paragraph (d) of this section. The consistency of the finished food is such that the time of flow is less than 30 seconds when tested by the method set forth in "Consistency Measurement of Fruit Nectars and Fruit Juice Products" published in the "Journal of the Association of Official Agricultural Chemists," pages 411–416, vol. 42, 1959. The food is sealed in a container and so processed by heat, either before or after sealing, as to prevent spoilage.

(b) (1) The fruit juice ingredients referred to in paragraph (a) of this section are pineapple juice, concentrated pineapple juice, grapefruit juice, and concentrated grapefruit juice. Each fruit juice ingredient may contain finely divided insoluble fruit solids but does not contain seeds, pits, or other coarse or hard substances capable of being avoided in good canning practices. The adjusted weight of the combination of these fruit juice ingredients shall be not less than 50 percent of the weight of the finished food, calculated by the method specified in paragraph (b)(2) of this section. Each fruit juice ingredient shall be used in a quantity sufficient to impart its characteristics to the blend, and the proportion of the pineapple juice ingredient shall exceed the proportion of the grapefruit juice ingredient.

(2) Determine the percent of soluble solids in the fruit juice ingredients used by the method prescribed in section 29.011 of "Official Methods of Analysis of the Association of Official Agricultural Chemists," 10th edition, 1965, page 487, under "Solids." Use this method, notwithstanding the presence of insoluble solids. Multiply the result so found by the weight of each fruit juice ingredient used and divide the product by the following Brix value for each fruit ingredient.

Name of fruit:	*Brix value*
Pineapple juice	13.0
Grapefruit juice	9.5

The result is the adjusted weight of the fruit juice ingredient. For example, assume there is on hand 1,300 pounds of concentrated pineapple juice that in accordance with the above-cited A.O.A.C. method is found to contain 30 percent of soluble solids. The weight of equivalent single strength pineapple juice is calculated as follows:

$$1{,}300 \times 30 \div 13.0 = 3{,}000 \text{ pounds}$$

(c) The optional sweetening ingredients referred to in paragraph (a) of this section are: Sugar, invert sugar sirup, dextrose, corn sirup, dried corn sirup, glucose sirup, and dried glucose sirup.

(d) Optional ingredients that may be added in making pineapple-grapefruit juice drink are one or more of the following:

(1) Citrus oil flavoring derived from orangé, lemon, and/or grapefruit.

(2) Acidifiers: Lemon juice, concentrated lemon juice, citric acid, malic acid, and fumaric acid.

(3) Ascorbic acid (vitamin C) added in such a quantity that the total ascorbic acid in each 4 fluid ounces of the finished pineapple-grapefruit juice drink amounts to not less than 30 milligrams and not more than 60 milligrams.

(4) Sodium citrate.

(e) The name of the food is:

Pineapple-Grapefruit Juice Drink
Contains not less than 50 percent fruit juice

That part of the name consisting of the statement "Contains not less than 50 percent fruit juice" shall immediately follow the words "Pineapple-grapefruit juice drink" and shall be shown in the same color, on the same background, and in letters that are not less than one-half the height of the largest letter in the preceding words in the name.

(f) The common names of the optional ingredients used shall be shown on the principal display panel or panels of the label with such prominence and conspicuousness that they are likely to be read and understood by ordinary individuals under customary conditions of purchase. The term "sweetener added" may be used in lieu of the name or names of the sweetening ingredient. The term "flavor added" may be used in lieu of the name of the citrus oil flavoring ingredient. When ascorbic acid (vitamin C) is added it shall be declared as "vitamin C added" or "with added vitamin C" and this declaration shall be accompanied by labeling conforming to the requirements prescribed in the regulations established pursuant to section 403(j) of the Federal Food, Drug, and Cosmetic Act.

NOTE.—§ 146.133 (formerly § 27.125) was stayed in its entirety at 33 FR 10713, July 27, 1968.

§ 146.135 Orange juice.

(a) Orange juice is the unfermented juice obtained from mature oranges of the species *Citrus sinensis*. Seeds (except embryonic seeds and small fragments of seeds that cannot be separated by good manufacturing practice) and excess pulp are removed. The juice may be chilled, but it is not frozen.

(b) The name of the food is "orange juice". The name "orange juice" may be preceded on the label by the varietal name of the oranges used, and if the oranges grew in a single State, the name of such State may be included in the name, as for example, "California Valencia orange juice".

§ 146.137 Frozen orange juice.

(a) Frozen orange juice is orange juice as defined in § 146.135, except that it is frozen.

(b) The name of the food is "Frozen orange juice". Such name may be preceded on the label by the varietal name of the oranges used, and if the oranges grew in a single State, the name of such State may be included in the name, as for example, "California Valencia frozen orange juice".

§ 146.140 Pasteurized orange juice.

(a) Pasteurized orange juice is the food prepared from unfermented juice obtained from mature oranges as specified in § 146.135, to which may be added not more than 10 percent by volume of the unfermented juice obtained from mature oranges of the species *Citrus reticulata* or hybrids thereof. Seeds (except embryonic seeds and small fragments of seeds that cannot be separated by good manufacturing practice) are removed, and pulp and orange oil may be adjusted in accordance with good manufacturing practice. If the adjustment involves the addition of pulp, then such pulp shall not be of the washed or spent type. The solids may be adjusted by the addition of one or more of the optional concentrated orange juice ingredients specified in paragraph (b) of this section. One or more of the optional sweetening ingredients listed in paragraph (c) of this section may be added in a quantity reasonably necessary to raise the Brix or the Brix-acid ratio to any point within the normal range usually found in unfermented juice obtained from mature oranges as specified in § 146.135. The orange juice is so treated by heat as to reduce substantially the enzymatic activity and the number of viable microorganisms. Either before or after such heat treatment, all or a part of the product may be frozen. The finished pasteurized orange juice contains not less than 10.5 percent by weight of orange juice soluble solids, exclusive of the solids of any added optional sweetening ingredients, and the ratio of the Brix hydrometer reading to the grams of anhydrous citric acid per 100 milliliters of juice is not less than 10 to 1.

(b) The optional concentrated orange juice ingredients referred to in paragraph (a) of this section are frozen concentrated orange juice as specified in § 146.146 and concentrated orange juice for manufacturing as specified in § 146.153 when made from mature oranges; but the quantity of such concentrated orange juice ingredients added shall not contribute more than one-fourth of the total orange juice solids in the finished pasteurized orange juice.

(c) The optional sweetening ingredients referred to in paragraph (a) of this section are sugar, invert sugar, dextrose, dried corn sirup, dried glucose sirup.

(d) (1) The name of the food is "Pasteurized orange juice". If the food is filled into containers and preserved by freezing, the label shall bear the name "Frozen pasteurized orange juice". The words "pasteurized" or "frozen pasteurized" shall be shown on labels in letters not less than one-half the height of the letters in the words "orange juice".

(2) If the pasteurized orange juice is filled into containers and refrigerated, the label shall bear the name of the food,

"chilled pasteurized orange juice". If it does not purport to be either canned orange juice or frozen pasteurized orange juice, the word "chilled" may be omitted from the name. The words "pasteurized" or "chilled pasteurized" shall be shown in letters not less than one-half the height of the letters in the words "orange juice".

(e) (1) If a concentrated orange juice ingredient specified in paragraph (b) of this section is used in adjusting the orange juice solids of the pasteurized orange juice, the label shall bear the statement "prepared in part from concentrated orange juice" or "with added concentrated orange juice" or "concentrated orange juice added".

(2) If one or more of the sweetening ingredients specified in paragraph (c) of this section are added to the pasteurized orange juice, the label shall bear the statement "____ added", the blank being filled in with the name or an appropriate combination of the names of the sweetening ingredients used. However, for the purpose of this section, the name "sweetener" may be used in lieu of the specific name or names of the sweetening ingredients.

(f) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements specified in this section for naming the optional ingredients used shall immediately and conspicuously precede or follow the name of the food, without intervening written, printed, or graphic matter.

§ 146.141 Canned orange juice.

(a) Canned orange juice is the food prepared from orange juice as specified in § 146.135 or frozen orange juice as specified in § 146.137, or a combination of both, to which may be added not more than 10 percent by volume of the unfermented juice obtained from mature oranges of the species *Citrus reticulata* or hybrids thereof. Seeds (except embryonic seeds and small fragments of seeds that cannot be separated by good manufacturing practice) are removed. Orange oil and pulp may be adjusted in accordance with good manufacturing practice. The adjustment of pulp referred to in this paragraph does not permit the addition of washed or spent pulp. Liquid condensate recovered from the deoiling operation may be added back. One or more of the optional sweetening ingredients named in paragraph (b) of this section may be added, in a quantity reasonably necessary to raise the Brix or the Brix-acid ratio to any point within the normal range usually found in unfermented juice obtained from mature oranges as specified in § 146.135. The food is sealed in containers and so processed by heat, either before or after sealing, as to prevent spoilage. The finished canned orange juice tests not less than 10° Brix, and the ratio of the Brix hydrometer reading to the grams of anhydrous citric acid per 100 milliliters of juice is not less than 9 to 1.

(b) The optional sweetening ingredients referred to in paragraph (a) of this section are sugar, invert sugar, dextrose, dried corn sirup, dried glucose sirup.

(c) The name of the food is "Canned orange juice". All the words in the name shall appear in the same size, color, and style of type and on the same color-contrasting background. If the food is not sold under refrigeration and if it does not purport to be chilled pasteurized orange juice or frozen pasteurized orange juice, the word "canned" may be omitted from the name.

(d) If one or more of the sweetening ingredients specified in paragraph (b) of this section are added to the canned orange juice, the label shall bear the statement "_____ added", the blank being filled in with the name or an appropriate combination of the names of the sweetening ingredients used. However, for the purpose of this section, the name "sweetener" may be used in lieu of the specific name or names of the sweetening ingredients.

(e) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in this section for naming the optional ingredients used shall immediately and conspicuously precede or follow the name of the food, without intervening written, printed, or graphic matter.

§ 146.145 Orange juice from concentrate.

(a) Orange juice from concentrate is the food prepared by mixing water with frozen concentrated orange juice as defined in § 146.146 or with concentrated orange juice for manufacturing as defined in § 146.153 (when made from mature oranges), or both. To such mixture may be added orange juice as defined in § 146.135, frozen orange juice as defined in § 146.137, pasteurized orange juice as defined in § 146.140, orange juice for manufacturing as defined in § 146.151 (when made from mature oranges and preserved by chilling or freezing but not by canning), orange oil, orange pulp, and one or more of the sweetening ingredients listed in paragraph (b) of this section. The finished orange juice from concentrate contains not less than 11.8 percent orange juice soluble solids, exclusive of solids of any added optional sweetening ingredients. It may be so treated by heat as to reduce substantially the enzymatic activity and the number of viable microorganisms.

(b) The sweetening ingredients referred to in paragraph (a) of this section are sugar, sugar sirup, invert sugar, invert sugar sirup, dextrose, corn sirup, dried corn sirup, glucose sirup, dried glucose sirup.

(c) The name of the food is "Orange juice from concentrate". The words "from concentrate" shall be shown in letters not less than one-half the height of the letters in the words "orange juice".

(d) When orange juice from concentrate contains any optional sweetening ingredient as listed in paragraph (b) of this section, whether added directly as such or indirectly as an added ingredient of any orange juice product used, the label shall bear the statement "_____ added", the blank being filled in with the name or an appropriate combination of the names of the sweetening ingredients added. However, for the purposes of this section the name "sweetener" may be used in lieu of the specific name or names of the sweetening ingredients.

(e) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements specified in this section for naming the optional ingredients used shall immediately and conspicuously precede or follow the name of the food, without intervening written, printed, or graphic matter.

§ 146.146 Frozen concentrated orange juice.

(a) Frozen concentrated orange juice is the food prepared by removing water from the juice of mature oranges as provided in § 146.135, to which juice may be added unfermented juice obtained from mature oranges of the species *Citrus reticulata*, or hybrids thereof, or of *Citrus aurantium*, or both. However, in the unconcentrated blend the volume of juice from *Citrus reticulata* shall not exceed 10 percent and from *Citrus aurantium* shall not exceed 5 percent. The concentrate so obtained is frozen. In its preparation, seeds (except embryonic seeds and small fragments of seeds that cannot be separated by good manufacturing practice) and excess pulp are removed, and a properly prepared water extract of the excess pulp so removed may be added. Orange oil, orange pulp, orange essence (obtained from orange juice), orange juice and other orange juice concentrate as provided in this section or concentrated orange juice for manufacturing provided in § 146.153 (when made from mature oranges), water, and one or more of the optional sweetening ingredients specified in paragraph (b) of this section may be added to adjust the final composition. The juice of *Citrus reticulata* and *Citrus aurantium*, as permitted by this paragraph, may be added in single strength or concentrated form prior to concentration of the *Citrus sinensis* juice, or in concentrated form during adjustment of the composition of the finished food. The addition of concentrated juice from *Citrus reticulata* or *Citrus aurantium*, or both, shall not exceed, on a single-strength basis, the 10 percent maximum for *Citrus reticulata* and the 5 percent maximum for *Citrus aurantium* prescribed by this paragraph. Any of the ingredients of the finished concentrate may have been so treated by heat as to reduce substantially the enzymatic activity and the number of viable microorganisms. The finished food is of such concentration that when diluted according to label directions the diluted article will contain not less than 11.8 percent by weight of orange juice soluble solids, exclusive of the solids of any added optional sweetening ingredients. The dilution ratio shall be not less than 3 plus 1. For the purposes of this section and § 146.150, the term "dilution ratio" means the whole number of volumes of water per volume of frozen concentrate re-

quired to produce orange juice from concentrate having orange juice soluble solids of not less than 11.8 percent by weight exclusive of the solids of any added optional sweetening ingredients.

(b) The optional sweetening ingredients referred to in paragraph (a) of this section are sugar, sugar sirup, invert sugar, invert sugar sirup, dextrose, corn sirup, dried corn sirup, glucose sirup, and dried glucose sirup.

(c) If one or more of the sweetening ingredients specified in paragraph (b) of this section are added to the frozen concentrated orange juice, the label shall bear the statement "_____ added", the blank being filled in with the name or an appropriate combination of names of the sweetening ingredients used. However, for the purpose of this section, the name "sweetener" may be used in lieu of the specific name or names of the sweetening ingredients.

(d) The name of the food concentrated to a dilution ratio of 3 plus 1 is "frozen concentrated orange juice" or "frozen orange juice concentrate". The name of the food concentrated to a dilution ratio greater than 3 plus 1 is "frozen concentrated orange juice, _____ plus 1" or "frozen orange juice concentrate, _____ plus 1", the blank being filled in with the whole number showing the dilution ratio; for example, "frozen orange juice concentrate, 4 plus 1". However, where the label bears directions for making 1 quart of orange juice from concentrate (or multiples of a quart), the blank in the name may be filled in with a mixed number; for example, "frozen orange juice concentrate, 4⅓ plus 1". For containers larger than 1 pint, the dilution ratio in the name may be replaced by the concentration of orange juice soluble solids in degrees Brix; for example, a 62° Brix concentrate in 3½-gallon cans may be named on the label "frozen concentrated orange juice, 62° Brix".

(e) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements specified in this section for naming the optional ingredients used shall immediately and conspicuously precede or follow the name of the food, without intervening written, printed, or graphic matter.

(f) Nothing in this section is intended to interfere with the adoption and enforcement by any State, in regulating the production of frozen concentrated orange juice in such State, of State standards, consistent with this section, but which impose higher or more restrictive requirements than those set forth in this section.

§ 146.150 Canned concentrated orange juice.

(a) Canned concentrated orange juice complies with the requirements for composition, definition of dilution ratio, and labeling of optional ingredients prescribed for frozen concentrated orange juice by § 146.146, except that it is not frozen and it is sealed in containers and so processed by heat, either before or after sealing, as to prevent spoilage.

(b) The name of the food when concentrated to a dilution ratio of 3 plus 1 is "Canned concentrated orange juice" or "Canned orange juice concentrate". The name of the food when concentrated to a dilution ratio greater than 3 plus 1 is "Canned concentrated orange juice, _____ plus 1" or "Canned orange juice concentrate, _____ plus 1", the blank being filled in with the whole number showing the dilution ratio; for example, "Canned orange juice concentrate, 4 plus 1". However, where the label bears directions for making 1 quart of single-strength diluted product (or multiples of a quart) the blank in the name may be filled in with a mixed number; for example, "Canned orange juice concentrate, 4⅓ plus 1". For containers larger than 1 pint, the dilution ratio in the name may be replaced by the concentration of orange juice soluble solids in degrees Brix; for example, a 62° Brix concentrate in 1-gallon cans may be named on the label "canned concentrated orange juice, 62° Brix". If the food does not purport to be frozen concentrated orange juice, the word "canned" may be omitted from the name.

§ 146.151 Orange juice for manufacturing.

(a) Orange juice for manufacturing is the food prepared for further manufacturing use. It is prepared from unfermented juice obtained from oranges as provided in § 146.135, except that the oranges may deviate from the standards for maturity in that they are below the minimum for Brix and Brix-acid ratio for such oranges, and to which juice may be added not more than 10 percent by volume of the unfermented juice obtained from oranges of the species *Citrus reticulata* or the hybrids thereof. Seeds (except embryonic seeds and small fragments of seeds that cannot be separated by good manufacturing practice) are removed, and pulp and orange oil may be adjusted in accordance with good manufacturing practice. If pulp is added it shall be other than washed or spent pulp. The juice or portions thereof may be so treated by heat as to reduce substantially the enzymatic activity and number of viable microorganisms, and it may be chilled or frozen, or it may be so treated by heat, either before or after sealing in containers, as to prevent spoilage.

(b) The name of the food is "Orange juice for manufacturing".

§ 146.152 Orange juice with preservative.

(a) Orange juice with preservative is the food prepared for further manufacturing use. It complies with the requirements for composition of orange juice for manufacturing as provided for in § 146.151, except that a preservative is added to inhibit spoilage. It may be heat-treated to reduce substantially the enzymatic activity and the number of viable microorganisms.

(b) The preservatives referred to in paragraph (a) of this section are sodium benzoate and sorbic acid. Sodium benzoate or sorbic acid may be used in an amount not exceeding 0.2 percent by weight.

(c) The name of the food is "Orange juice with preservative".

(d) The label shall bear the statement "_____ _____ added as a preservative", the first blank being filled in with the percent by weight of the preservative used and the second blank by the name "sorbic acid" or "sodium benzoate" (or "benzoate of soda"), as appropriate.

(e) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in paragraph (d) of this section for naming the preservative ingredient used shall immediately and conspicuously precede or follow the name of the food, without intervening written, printed, or graphic matter.

§ 146.153 Concentrated orange juice for manufacturing.

(a) Concentrated orange juice for manufacturing is the food that complies with the requirements for composition and labeling of optional ingredients prescribed for frozen concentrated orange juice by § 146.146, except that it is either not frozen, or it is less concentrated, or both, and the oranges from which the juice is obtained may deviate from the standards for maturity in that they are below the minima for Brix and Brix-acid ratio for such oranges: *Provided, however,* That the concentration of orange juice soluble solids is not less than 20° Brix.

(b) The name of the food is "Concentrated orange juice for manufacturing, _____" or "_____ orange juice concentrate for manufacturing", the blank being filled in with the figure showing the concentration of orange juice soluble solids in degrees Brix.

§ 146.154 Concentrated orange juice with preservative.

(a) Concentrated orange juice with preservative complies with the requirements for composition and labeling of optional ingredients prescribed for concentrated orange juice for manufacturing by § 146.153, except that a preservative is added to inhibit spoilage.

(b) The preservatives referred to in paragraph (a) of this section are sodium benzoate and sorbic acid. Sodium benzoate or sorbic acid may be used in an amount not exceeding 0.2 percent, by weight.

(c) The name of the food is "Concentrated orange juice with preservative, _____", the blank being filled in with the figure showing the concentration of orange juice soluble solids in degrees Brix.

(d) The label shall bear the statement "_____ _____ added as a preservative", the first blank being filled in with the percent by weight of the preservative used and the second blank by the name "sorbic acid" or "sodium benzoate" (or "benzoate of soda"), as appropriate.

(e) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in paragraph (d) of this section for naming the preservative ingredient used shall immediately and conspicuously precede or follow the name of the food, without intervening written, printed, or graphic matter.

§ 146.155 Orange juice drink.

(a) Orange juice drink is the beverage prepared by adding water to one or more of the unfermented orange juice ingredients which are specified in paragraph (b) of this section and which are used in quantities as indicated by paragraph (d) (2) of this section. One or more of the safe and suitable ingredients specified in paragraph (c) of this section may be added to the beverage. Vitamin C shall be added in a quantity which will ensure that the total vitamin C in each 6 fluid ounces of the finished beverage amounts to 60 milligrams. Orange juice drink may be preserved by freezing; by refrigerating; by heating to reduce substantially the enzymatic activity and the number of viable microorganisms; by sealing in containers and, either before or after sealing, heating to prevent spoilage; or by adding a preservative. For the purposes of this section orange juice drink contains less than 70 percent but not less than 35 percent equivalent single strength orange juice calculated as prescribed by paragraph (d) (2) of this section. This requirement is considered to have been met if the content of orange juice soluble solids (exclusive of soluble solids other than orange juice soluble solids), amounts to less than 8.26 percent but not less than 4.13 percent by weight of the finished beverage. The weight of the total solids is not less than 12 percent of the weight of the finished beverage.

(b) The classes of unfermented orange juice ingredients referred to in paragraph (a) of this section are:

(1) Orange juice products defined in §§ 146.135, 146.137, 146.140, 146.141, 146.145, 146.146, 146.150, 146.151, 146.152, 146.153, and 146.154 subject to the restriction that those defined in §§ 146.152 and 146.154 are used only in preparing orange juice drink which contains an added preservative as provided for in paragraph (a) of this section and that orange juice products so processed by heat as to prevent spoilage are used only in the canned form of the orange juice drink.

(2) Dehydrated orange juice made from oranges of the species *Citrus sinensis*.

(3) Water-extracted soluble orange solids as defined in § 146.168.

(4) Dehydrated water-extracted soluble orange solids as defined in § 146.169.

(5) Comminuted oranges as defined in § 146.170.

(6) Dehydrated comminuted oranges as defined in § 146.171.

(7) Extract of comminuted oranges as defined in § 146.172.

(8) Dehydrated extract of comminuted oranges as defined in § 146.175.

(9) Pulpy orange juice for manufacturing or juicy orange pulp for manufacturing as defined in § 146.176.

(10) Dehydrated pulpy orange juice for manufacturing or dehydrated juicy orange pulp for manufacturing as defined in § 146.177.

(11) Orange juice ingredients which conform to the compositional requirements of any one of the classes of orange juice ingredients described in paragraph (c) (1) through (10) of this section, except that the oranges from which they are made are oranges of the species *Citrus reticulata*, *Citrus aurantum*, hybrids thereof, or hybrids of the species *Citrus sinensis*.

(c) The safe and suitable ingredients provided for in paragraph (a) of this section that may be added to orange juice drink are one or more of the following:

(1) Nutritive sweeteners.
(2) Organic acids.
(3) Thickeners.
(4) Stabilizers.
(5) Clouding agents.
(6) Emulsifiers.
(7) Buffers.
(8) Orange pulp.
(9) Orange peel.
(10) Natural and artificial flavors.
(11) Natural and artificial colors.
(12) Preservatives.

For the purposes of this paragraph, an ingredient may be used in orange juice drink in such proportion as reasonably necessary to accomplish its intended effect. The ingredients of this paragraph are considered safe if they are not food additives or color additives within the meaning of section 201 (s) or (t) of the Federal Food, Drug, and Cosmetic Act or if they are food additives or color additives as so defined and are used in conformity with regulations established pursuant to section 409 or 706 of the act.

(d) (1) The name of the beverage consists of the following two phrases which shall appear together:

(i) The words "Orange juice drink" which shall be printed on a single line and shall all be in type of the same size and style.

(ii) The words "Containing ____ percent orange juice" which shall have the blank filled in with the number 35 or a number which is a multiple of 5 higher than 35 but not higher than 65 or greater than the percentage of equivalent single strength orange juice in the finished beverage. The word "Containing" may be on the line below "orange juice drink". The words "____ percent orange juice" shall all be on the line below "Containing" and shall be in bold condensed caps in letters all of the same size, the height of which is not less than:

(*a*) 12-point type if the container in which it is sold contains less than 16 ounces of the finished beverage and 14-point type if the container in which it is sold contains 16 ounces or more of the finished beverage; or

(*b*) One-half the height of the largest letters in which the word "juice" or "orange" appears anywhere on the labeling either directly or indirectly, such as by appearing as another form or derivative thereof or by the word "juice" or "orange" or any form or derivative thereof appearing as a part of a compound or fanciful word or name, or otherwise; whichever is the larger. All of the words in the name shall be in the same color type and on the same color contrasting background. If the beverage is preserved by freezing, the name shall be preceded by the word "frozen". If refrigeration is required to preserve the beverage the words "Keep refrigerated" shall appear on the principal display panel.

(2) The percentage of orange juice in the finished beverage is determined by adding the weight of orange juice soluble solids (exclusive of the weight of soluble solids other than orange juice soluble solids) contributed to the finished beverage by each of the added orange juice ingredients and dividing the sum of those weights by the product obtained by multiplying 11.8 percent by the total weight of the finished beverage. For the purpose of calculating the percentage of orange juice that shall be declared on the label, if the sum of the weights of the orange juice soluble solids contributed to the finished beverage by the orange juice ingredients described in paragraph (b) (3) through (11) of this section exceeds 1.18 percent of the weight of the finished beverage, then only so much of the sum of those weights as equals 1.18 percent of the weight of the finished beverage shall be counted as orange juice. The remaining orange juice soluble solids declared on the label must be contributed by one or more of the orange juice ingredients described in paragraph (b) (1) or (2) of this section.

(e) The common name of each of the ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter, and the vitamin C shall be declared as such in conformity with the requirements prescribed in the regulations established pursuant to section 403(j) of the act except that:

(1) If an orange juice product or products provided for in paragraph (b) (1) and (2) of this section is used, the words "orange juice" may be used in lieu of the common or usual name of the orange juice product provided for by the applicable section.

(2) If an orange juice ingredient or ingredients provided for in paragraph (b) (3) through (11) is used, the words "orange component" may be used in lieu of the common or usual name of the orange juice ingredient provided for by the applicable section.

(3) If sugar (sucrose) or invert sugar is used the term "sweetener" may be used, and if the sweetener is derived from corn the term "corn sweetener" may be used.

Further, the declaration of the ingredients on the label as set out in this paragraph shall appear in letters not less than one-half of that required by § 101.105 of this chapter for the declaration of net quantity of contents.

NOTE.—§ 146.155 (formerly § 27.158) was stayed in its entirety at 38 FR 6969, Mar. 14, 1973.

§ 146.156 Concentrate for orange juice drink.

Concentrate for orange juice drink is the beverage concentrate which, when diluted according to label directions, conforms to all of the requirements for composition and labeling prescribed by § 146.155 for orange juice drink except that:

(a) The name of the concentrated beverage base consists of the following two phrases which shall appear together:

(1) The words "Concentrate for" which shall be on a single line immediately above the words "Orange juice drink".

(2) The words "Containing ____ percent orange juice" which shall have the blank filled in with the number 35 or a number which is a multiple of 5 higher than 35 but not higher than 65 or greater than the percentage of equivalent single strength orange juice in the beverage made by diluting the beverage concentrate as directed on the label.

(b) The dilution ratio of the beverage shall be not less than 3 plus 1. For the purpose of this section the "dilution ratio" is the whole number of volumes of water per volume of concentrate for orange juice drink required to produce orange juice drink conforming to the requirements for composition prescribed by § 146.155.

NOTE.—§ 146.156 (formerly § 27.159) was stayed in its entirety at 38 FR 6969, Mar. 14, 1973.

§ 146.158 Powdered orange juice drink.

Powdered orange juice drink is the dehydrated beverage base which, when reconstituted according to label directions, conforms to all of the requirements for composition and labeling as prescribed by § 146.155 for orange juice drink except that:

(a) The name of the beverage base consists of the following two phrases which shall appear together:

(1) The word "Powdered" or any appropriate descriptive word used in lieu of the word "Powdered" which shall be on a line immediately above the words "Orange juice drink".

(2) The words "Containing _____ percent orange juice" which shall have the blank filled in with the number 35 or a number which is a multiple of 5 higher than 35 but not higher than 65 or greater than the percentage of equivalent single strength orange juice in the beverage made by reconstituting the powdered base as directed on the label.

(b) Safe and suitable anticaking agents, foaming agents, browning inhibitors, and drying agents may be added.

NOTE.—§ 146.158 (formerly § 27.160) was stayed in its entirety at 38 FR 6969, Mar. 14, 1973.

§ 146.159 Orange juice drink blend.

Orange juice drink blend is the beverage that conforms to all of the requirements for composition and labeling prescribed by § 146.155 for orange juice drink, except that:

(a) It is prepared by adding water to a blend of the orange juice ingredients set forth in § 146.155(b) and derived from fruit grown in two or more geographic orange producing regions with a minimum of 20 percent of the orange juice soluble solids derived from fruit grown in any one producing region. Orange juice soluble solids derived from the orange juice ingredients set forth in § 146.155(b) (3) to (11) are not counted toward the above requirement for the minimum of 20 percent of the orange juice soluble solids to be derived from fruit grown in any one producing region but may be added in quantities as indicated in § 146.155(d)(2).

(b) It contains less than 95 percent but not less than 70 percent equivalent single strength orange juice calculated as indicated in § 146.155(d)(2). This requirement is considered to have been met if the content of orange juice soluble solids (exclusive of soluble solids other than orange juice soluble solids) amounts to less than 11.2 percent but not less than 8.26 percent by weight of the finished beverage.

(c) Thickeners, stabilizers, clouding agents, emulsifiers, and buffers may not be added to orange juice drink blend.

(d) The name of the beverage consists of the following two phrases which shall appear together:

(1) The words "Orange juice drink blend" which shall be printed on a single line.

(2) The words "Containing ____ percent orange juice" which shall have the blank filled in with the number 70 or a number which is a multiple of 5 higher than 70 but not higher than 95 or greater than the percentage of equivalent single strength orange juice in the beverage.

NOTE.—§ 146.159 (formerly § 27.161) was stayed in its entirety at 38 FR 6969, Mar. 14, 1973.

§ 146.160 Powdered orange juice drink blend.

Powdered orange juice drink blend is the dehydrated beverage base which, when reconstituted according to label directions, conforms to all of the requirements for composition and labeling prescribed by § 146.159 for orange juice drink blend except that:

(a) The name of the beverage base consists of the following two phrases which shall appear together:

(1) The word "Powdered" or any appropriate descriptive word used in lieu of the word "Powdered" which shall be on a line immediately above the words "Orange juice drink blend".

(2) The words "Containing _____ percent orange juice" which shall have the blank filled in with the number 70 or a number which is a multiple of 5 higher than 70 but not higher than 95 or greater than the percentage of equivalent single strength orange juice contained in a beverage made by reconstituting the powdered base as directed on the label.

(b) Safe and suitable anticaking agents, foaming agents, browning inhibitors, and drying agents may be added.

NOTE.—§ 146.160 (formerly § 27.162) was stayed in its entirety at 38 FR 6969, Mar. 14, 1973.

§ 146.161 Orange drink.

Orange drink is the beverage that conforms to all of the requirements for composition and labeling prescribed by § 146.155 for orange juice drink except that:

(a) It contains less than 35 percent but not less than 10 percent equivalent single strength orange juice calculated as set forth in § 146.155(d)(2). This requirement is considered to have been met if the content of orange juice soluble solids (exclusive of soluble solids other than orange juice soluble solids) amounts to less than 4.13 percent but not less than 1.18 percent by weight of the finished beverage.

(b) The minimum orange juice soluble solids requirement of 1.18 percent for orange drink may be contributed solely by one or more of the orange juice ingredients described in § 146.155(b) (3) through (11). The remaining orange juice soluble solids declared on the label, if more than 10 percent is declared, must be contributed by one or more of the orange juice ingredients described in § 146.155(b) (1) and (2).

(c) The weight of the total soluble solids is not less than 10 percent by weight of the finished beverage.

(d) The name of the beverage consists of the following two phrases which shall appear together:

(1) The words "Orange drink" which shall be printed on a single line.

(2) The words "Containing _____ percent orange juice" which shall have the blank filled in with the number 10 or a number which is a multiple of 5 higher than 10 but not higher than 30 or greater than the percentage of equivalent single strength orange juice contained in the finished beverage.

NOTE.—§ 146.161 (formerly § 27.163) was stayed in its entirety at 38 FR 6969, Mar. 14, 1973.

§ 146.163 Concentrate for orange drink.

Concentrate for orange drink is the beverage concentrate which, when diluted according to label directions, conforms to all of the requirements for composition and labeling prescribed by § 146.161 for orange drink except that:

(a) The name of the concentrated beverage base consists of the following two phrases which shall appear together:

(1) The words "Concentrate for" which shall be on a single line immediately above the words "Orange drink".

(2) The words "Containing ____ percent orange juice" which shall have the blank filled in with the number 10 or a number which is a multiple of 5 higher than 10 but not higher than 30 or greater than the percentage of equivalent single strength orange juice in the beverage made by diluting the beverage concentrate as directed on the label.

(b) The dilution ratio of the beverage shall be not less than 3 plus 1. For the purposes of this section, the "dilution ratio" is the whole number of volumes

of water per volume of concentrate for orange drink required to produce orange drink conforming to the requirements for composition prescribed by § 146.161.

NOTE.—§ 146.163 (formerly § 27.164) was stayed in its entirety at 38 FR 6969, Mar. 14, 1973.

§ 146.164 Powdered orange drink.

Powdered orange drink is the dehydrated beverage base which, when reconstituted according to label directions, conforms to all of the requirements for composition and labeling prescribed by § 146.161 for orange drink except that:

(a) The name of the beverage base consists of the following two phrases which shall appear together:

(1) The word "Powdered" or any appropriate descriptive word used in lieu of the word "Powdered" which shall be on a line immediately above the words "Orange drink".

(2) The words "Containing ____ percent orange juice" which shall have the blank filled in with the number 10 or a number which is a multiple of 5 higher than 10 but not higher than 30 or greater than the percentage of equivalent single strength orange juice in a beverage made by reconstituting the powdered base as directed on the label.

(b) Safe and suitable anticaking agents, foaming agents, browning inhibitors, and drying agents may be added.

NOTE.—§ 146.164 (formerly § 27.165) was stayed in its entirety at 38 FR 6969, Mar. 14, 1973.

§ 146.165 Orange flavored drink.

Orange flavored drink is the beverage that conforms to all of the requirements for composition and labeling prescribed by § 146.155 for orange juice drink except that:

(a) It contains less than 10 percent but more than 0 percent equivalent single strength orange juice calculated as set forth in § 146.155(d)(2) of this chapter. This requirement is considered to have been met if the content of orange juice soluble solids (exclusive of soluble solids other than orange juice soluble solids) amounts to less than 1.18 percent but more than 0 percent by weight of the finished beverage.

(b) The orange juice soluble solids requirements for orange flavored drink may be contributed solely by one or more of the orange juice ingredients described in § 146.155(b) (1) through (11).

(c) The weight of the total soluble solids is not less than 10 percent by weight of the finished beverage.

(d) The name of the beverage consists of the following two phrases which shall appear together:

(1) The words "Orange flavored drink" which shall be printed on a single line.

(2) The words "Containing ____ percent orange juice" which shall have the blank filled in with the words "less than 2" if the beverage contains less than 2 percent but more than 0 percent orange juice or with the number 2 or a number which is a multiple of 2 higher than 2 but not higher than 8 or greater than the percentage of equivalent single strength orange juice contained in the finished beverage.

NOTE.—§ 146.165 (formerly § 27.166) was stayed in its entirety at 38 FR 6969, Mar. 14, 1973.

§ 146.166 Concentrate for orange flavored drink.

Concentrate for orange flavored drink is the beverage concentrate which, when diluted according to label directions, conforms to all of the requirements for composition and labeling prescribed by § 146.165 for orange flavored drink except that:

(a) The name of the concentrated beverage base consists of the following two phrases which shall appear together:

(1) The words "Concentrate for" which shall be on a single line immediately above the words "Orange flavored drink".

(2) The words "Containing ____ percent orange juice" which shall have the blank filled in with the words "less than 2" or with the number 2 or a number which is a multiple of 2 higher than 2 but not higher than 8 or greater than the percentage of equivalent single strength orange juice in a beverage made by diluting the beverage concentrate as directed on the label.

(b) The dilution ratio of the beverage shall not be less than 3 plus 1. For the purpose of this section the "dilution ratio" is the whole number of volumes of water per volume of concentrate for orange flavored drink required to produce orange flavored drink conforming to the requirements for composition prescribed by § 146.165.

NOTE.—§ 146.166 (formerly § 27.167) was stayed in its entirety at 38 FR 6969, Mar. 14, 1973.

§ 146.167 Powdered orange flavored drink.

Powdered orange flavored drink is the dehydrated beverage base which when reconstituted according to label directions conforms to all of the requirements for composition and labeling as prescribed by § 146.165 for orange flavored drink except that:

(a) The name of the beverage base consists of the following two phrases which shall appear together:

(1) The word "Powdered" or any appropriate descriptive word used in lieu of the word "Powdered" which shall be on a line immediately above the words "Orange flavored drink".

(2) The words "Containing ____ percent orange juice" which shall have the blank filled in with the words "less than 2" or with the number 2 or a number which is a multiple of 2 higher than 2 but not higher than 8 or greater than the percentage of equivalent single strength orange juice in a beverage made by reconstituting the powdered base as directed on the label.

(b) Safe and suitable anticaking agents, foaming agents, browning inhibitors, and drying agents may be added.

NOTE: § 146.167 (formerly § 27.168) was stayed in its entirety at 38 FR 6969, Mar. 14, 1973.

§ 146.168 Water-extracted soluble orange solids.

(a) Water-extracted soluble orange solids is the food prepared for further manufacturing use from the unfermented excess pulp removed during the production of one or more of the orange juice products provided for in §§ 146.135, 146.137, 146.140, 146.141, 146.145, 146.146, 146.150, 146.151, 146.152, 146.153, and 146.154. The orange juice adhering to the excess pulp is extracted from the excess pulp in the presence of water. Seeds (except embryonic seeds and small fragments of seeds that cannot be separated by good manufacturing practice) and part of the spent pulp are removed. Water may be removed. The food may be preserved by freezing; by refrigerating; by adding a safe and suitable optional preservative ingredient; by heating to reduce substantially the enzymatic activity and the number of viable microorganisms; or by heating, either before or after sealing in containers, to prevent spoilage.

(b) An optional ingredient is considered to be safe if it is not a food additive as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act, or if it is a food additive as so defined and is used in conformity with regulations established pursuant to section 409 of the act.

(c) The name of the food is "water-extracted soluble orange solids __° Brix", the blank being filled in with the figure showing the percent by weight of total soluble orange solids in the food expressed in degrees Brix. However, if the food is concentrated to 20° Brix or more, the word "concentrated" shall precede the name of the food.

(d) If one or more of the optional preservative ingredients are added, the label shall bear the statement "_____ added as a preservative", the blank being filled in with the name of the preservative.

(e) For the purpose of calculating the percentage of orange juice in a beverage to which this food is added as an optional orange juice ingredient use the weight of only the soluble portion of this food in calculating the percentage of orange juice soluble solids that may be contributed to the beverage by this food.

NOTE.—§ 146.168 (formerly § 27.150) was stayed in its entirety at 38 FR 6969, Mar. 14, 1973.

§ 146.169 Dehydrated water-extracted soluble orange solids.

(a) Dehydrated water-extracted soluble orange solids is the dehydrated food for further manufacturing use prepared by removing water from water-extracted soluble orange solids as defined in § 146.168. Orange essence and orange oil may be added. It may contain one or more of the safe and suitable ingredients specified in paragraph (b) of this section. The moisture content is not greater than 7 percent of the weight of the finished food. It may be refrigerated or frozen.

(b) The optional ingredients suitable for use in the dehydrated food are the following:

(1) Anticaking agents.
(2) Antioxidants.
(3) Foaming agents.
(4) Browning inhibitors.
(5) Drying agents.

For the purposes of this section, an optional ingredient is considered to be safe when it complies with the requirements of § 146.168(b).

(c) The common name of each of the ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter and shall appear in letters not less than one-half the size required by § 101.105 of this chapter for the declaration of net quantity of contents.

(d) The name of the food is "Dehydrated water-extracted soluble orange solids".

(e) For the purpose of calculating the percentage of orange juice in a beverage to which this food is added as an optional orange juice ingredient, use only the weight of the soluble portion of the food in calculating the percentage of orange juice soluble solids that may be contributed to the beverage by this food.

NOTE.—§ 146.169 (formerly § 27.151) was stayed in its entirety at 38 FR 6969, Mar. 14, 1973.

§ 146.170 Comminuted oranges.

(a) Comminuted oranges is the food puree for further manufacturing use prepared by comminuting whole mature oranges of the species *Citrus sinensis*. The amount of orange oil may be adjusted in accordance with good manufacturing practice. Orange essence may be added. The food may be preserved by freezing; by refrigerating; by adding a safe and suitable preservative; by heating to reduce substantially the enzymatic activity and the number of viable microorganisms; or by heating, either before or after sealing in containers, to prevent spoilage.

(b) For the purposes of this section, a preservative is considered to be safe when it complies with the requirements of § 146.168(b).

(c) The name of the food is "Comminuted oranges _____ percent Brix", the blank being filled in with the figure showing the percent by weight of total soluble orange solids in the food expressed in degrees Brix.

(d) If a preservative is added the label shall bear the statement "_____ added as a preservative", the blank being filled in with the name of the preservative.

(e) For the purpose of calculating the percentage of orange juice in a beverage to which this food is added as an optional orange juice ingredient, use only the weight of the soluble portion of the food in calculating the percentage of orange juice soluble solids that may be contributed to the beverage by this food.

NOTE.—§ 146.170 (formerly § 27.152) was stayed in its entirety at 38 FR 6969, Mar. 14, 1973.

§ 146.171 Dehydrated comminuted oranges.

(a) Dehydrated comminuted oranges is the dehydrated food for further manufacturing use prepared by removing water from comminuted oranges as defined in § 146.170. The food complies with the requirements for composition and labeling of optional ingredients prescribed for dehydrated water-extracted soluble orange solids by § 146.169, except that it is made from comminuted oranges as defined in § 146.170 and except that the moisture content is not greater than 10 percent of the weight of the finished food.

(b) The name of the food is "Dehydrated comminuted oranges".

(c) For the purpose of calculating the percentage of orange juice in a beverage to which this food is added as an optional orange juice ingredient, use only the weight of the soluble portion of the food in calculating the percentage orange juice soluble solids that may be contributed to the beverage by this food.

NOTE.—§ 146.171 (formerly § 27.153) was stayed in its entirety at 38 FR 6969, Mar. 14, 1973.

§ 146.172 Extract of comminuted oranges.

(a) Extract of comminuted oranges is the liquid food prepared for further manufacturing use from the fluids obtained from comminuted oranges as defined in § 146.170. Water may be used in the extraction process. Excess peel, pulp, flavido, and seed fragments are removed. Water may be removed. The amount of orange oil may be adjusted in accordance with good manufacturing practice. Orange essence may be added. The food may be preserved by freezing; by refrigerating; by adding a safe and suitable preservative; by heating to reduce substantially the enzymatic activity and the number of viable microorganisms; or by heating, either before or after sealing in containers, to prevent spoilage.

(b) For the purposes of this section, a preservative is considered to be safe if it complies with the requirements of § 146.168(b).

(c) The name of the food is "Extract of comminuted oranges, _____° Brix", the blank being filled in with the figure showing the percent by weight of total soluble solids in the food expressed in degrees Brix.

(d) If a preservative is added the label shall bear the statement "_____ added as a preservative", the blank being filled in with the name of the preservative.

(e) For the purpose of calculating the percentage of orange juice in a beverage to which this food is added as an optional orange juice ingredient, use only the weight of the soluble portion of the food in calculating the percentage of orange juice soluble solids that may be contributed to the beverage by this food.

NOTE.—§ 146.172 (formerly § 27.154) was stayed in its entirety at 38 FR 6969, Mar. 14, 1973.

§ 146.175 Dehydrated extract of comminuted oranges.

(a) Dehydrated extract of comminuted oranges is the dehydrated food for further manufacturing use prepared by removing water from extract of comminuted oranges as defined in § 146.172. The food complies with the requirements for composition and labeling of optional ingredients prescribed for dehydrated water-extracted soluble orange solids by § 146.169 except that it is made from extract of comminuted oranges as defined in § 146.172.

(b) The name of the food is "Dehydrated extract of comminuted oranges".

(c) For the purpose of calculating the percentage of orange juice in a beverage to which this food is added as an optional orange juice ingredient, use only the weight of the soluble portion of the food in calculating the percentage of orange juice soluble solids that may be contributed to the beverage by this food.

NOTE.—§ 146.175 (formerly § 27.155) was stayed in its entirety at 38 FR 6969, Mar. 14, 1973.

§ 146.176 Juicy orange pulp for manufacturing.

(a) Juicy orange pulp for manufacturing and pulpy orange juice for manufacturing is the class of pulpy moist foods or pulpy liquid foods prepared for further manufacturing use from the unfermented juice and the pulp of mature oranges of the species *Citrus sinensis*. The pulp has not been washed. Seeds (except embryonic seeds and small fragments of seeds that cannot be separated by good manufacturing practice) are removed. Orange juice, orange pulp, and orange oil may be adjusted in accordance with good manufacturing practice. Orange essence and orange juice products as defined in §§ 146.135, 146.137, 146.140, 146.141, 146.145, 146.146, 146.150, 146.151, 146.152, 146.153, and 146.154 may be added. The food may be preserved by freezing; by refrigerating; by adding a preservative; by heating to reduce substantially the enzymatic activity and the number of viable microorganisms; or by heating, either before or after sealing in containers, to prevent spoilage.

(b) For the purposes of this section, a preservative is considered to be safe if it complies with the requirements of § 146.168(b).

(c) The name of the food is "Juicy orange pulp for manufacturing", if the percentage of pulp exceeds 50 percent or the name of the food is "Pulpy orange juice for manufacturing", if the percentage of pulp is 50 percent or less.

(d) If a preservative is added, the label shall bear the statement "_____ added as a preservative", the blank being filled in with the name of the preservative.

(e) For the purpose of calculating the percentage of the orange juice in a beverage to which this food is added as an optional orange juice ingredient, use only the weight of the soluble portion of the food in calculating the percentage of orange juice soluble solids that may be contributed to the beverage by this food.

NOTE.—§ 146.176 (formerly § 27.156) was stayed in its entirety at 38 FR 6969, Mar. 14, 1973.

§ 146.177 Dehydrated juicy orange pulp for manufacturing.

(a) Dehydrated juicy orange pulp for manufacturing and dehydrated pulpy

orange juice for manufacturing is the class of dehydrated foods for further manufacturing use prepared by removing water from juicy orange pulp for manufacturing or pulpy orange juice for manufacturing as defined in § 146.176. The food complies with the requirements for composition and labeling of optional ingredients prescribed for dehydrated water-extracted soluble orange solids by § 146.169, except that it is made from juicy orange pulp or pulpy orange juice rather than from dehydrated water extracted soluble orange solids and except that the moisture content is not greater than 10 percent of the weight of the finished food.

(b) The name of the food is "Dehydrated juicy orange pulp for manufacturing", if it is made from juicy orange pulp for manufacturing, or the name of the food is "Dehydrated pulpy orange juice for manufacturing," if it is made from pulpy orange juice for manufacturing, both as defined in § 146.176.

(c) For the purpose of calculating the percentage of orange juice in a beverage to which this food is added as an optional orange juice ingredient use only the weight of the soluble portion of the food in calculating the percentage of orange juice soluble solids that may be contributed to the beverage by this food.

NOTE: § 146.177 (formerly § 27.157) was stayed in its entirety at 38 FR 6969, Mar. 14, 1973.

§ 146.185 Canned pineapple juice.

(a) *Identity*—(1) Canned pineapple juice is the juice, intended for direct consumption, obtained by mechanical process, which may include centrifuging but not filtering, from the flesh or parts thereof, with or without core material, of sound, ripe pineapple (*Ananas comosus* L. Merrill). The juice may have been concentrated and later reconstituted with water suitable for the purpose of maintaining essential composition and quality factors of the juice. Canned pineapple juice contains finely divided insoluble solids, but it does not contain pieces of shell, seeds, or other coarse or hard substances. It may be sweetened with any suitable dry nutritive carbohydrate sweetener. However, if the pineapple juice is prepared from concentrate, such sweeteners, in liquid form, also may be used. It may contain added vitamin C in a quantity such that the total vitamin C in each 4 fluid ounces of the finished food amounts to not less than 30 milligrams and not more than 60 milligrams. In the canning of pineapple juice, dimethylpolysiloxane complying with the requirements of § 173.340 of this chapter may be employed as a defoaming agent in an amount not greater than 10 parts per million by weight of the finished food. Before or after sealing in the container, canned pineapple juice is so processed by heat as to prevent spoilage.

(2) The name of the food is "Pineapple juice" if the juice from which it is prepared has not been concentrated and/or diluted with water. The name of the food is "Pineapple juice from concentrate" if the finished juice has been made from pineapple juice concentrate as specified in paragraph (a) of this section. If a nutritive sweetener is added, the label shall bear the statement "Sweetener added." If no sweetener is added, the word "Unsweetened" may immediately precede or follow the words "Pineapple juice" or "Pineapple juice from concentrate."

(3) Each of the optional ingredients shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(b) *Quality*—(1) The standard of quality for canned pineapple juice is as follows:

(i) The soluble solids content of pineapple juice (exclusive of added sugars) without added water shall not be less than 10.5° Brix as determined by refractometer at 20° C uncorrected for acidity and read as degrees Brix on International Sucrose Scales. Where the juice has been obtained using concentrated juice with addition of water, the soluble pineapple juice solids content (exclusive of added sugars) shall be not less than 13.5° Brix, uncorrected for acidity and read as degrees Brix on the International Sucrose Scales.

(ii) The acidity, as determined by the method prescribed in paragraph (b) (2) (ii) of this section, is not more than 1.35 grams of anhydrous citric acid per 100 milliliters of the juice.

(iii) The ratio of the degrees Brix to total acidity, as determined by the method prescribed in paragraph (b) (2) (iii) of this section, is not less than 12.

(iv) The quantity of finely divided "insoluble solids", as determined by the method prescribed in paragraph (b) (2) (iv) of this section, is not less than 5 percent nor more than 30 percent.

(2) The methods referred to in paragraph (b) (1) of this section are as follows:

(i) Determine the degrees Brix of the canned pineapple juice by the method prescribed in "Official Methods of Analysis of the Association of Official Agricultural Chemists," "Solids—By Means of Spindle—Official" [Ed. note, 10th edition, 1965, p. 486, sec. 29.009].

(ii) Determine the total acidity of the canned pineapple juice by titration by the method prescribed in § 145.180(b) (2) (ix) of this chapter.

(iii) Divide the degrees Brix determined as prescribed in paragraph (b) (2) (i) of this section by the grams of anhydrous citric acid per 100 milliliters of juice, determined as prescribed in paragraph (b) (2) (ii) of this section, and report the results as ratio of degrees Brix to total acidity.

(iv) Determine the quantity of "insoluble solids" in canned pineapple juice as follows: Measure 50 milliliters of thoroughly stirred pineapple juice into a cone-shaped graduated tube of the long-cone type, measuring approximately 4⅜ inches from tip to top calibration and having a capacity of 50 milliliters. Place the tube in a suitable centrifuge the approximate speed of which is related to diameter of swing in accordance with the table immediately below. The word "diameter" means the over-all distance between the tips of opposing centrifuge tubes in operating position.

Diameter (inches):	*Approximate revolutions per minute*
10	1,609
10½	1,570
11	1,534
11½	1,500
12	1,468
12½	1,438
13	1,410
13½	1,384
14	1,359
14½	1,336
15	1,313
15½	1,292
16	1,271
16½	1,252
17	1,234
17½	1,216
18	1,199
18½	1,182
19	1,167
19½	1,152
20	1,137

The milliliter reading at the top of the layer of "insoluble solids," after centrifuging 3 minutes, is multiplied by two to obtain the percentage of "insoluble solids."

(3) If the quality of canned pineapple juice falls below the standard prescribed in paragraph (b) (1) of this section, the label shall bear the general statement of substandard quality specified in § 130.14 (a) of this chapter, in the manner and form therein specified.

(c) *Fill of container*—(1) The standard of fill of container for canned pineapple juice is a fill of not less than 90 percent of the total capacity of the container, as determined by the general method for fill of container prescribed in § 130.12(b) of this chapter.

(2) If canned pineapple juice falls below the standard of fill of container prescribed in paragraph (c) (1) of this section, the label shall bear the statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

§ 146.187 Canned prune juice.

(a) Canned prune juice is the food prepared from a water extract of dried prunes and contains not less than 18.5 percent by weight of water-soluble solids extracted from dried prunes. The quantity of prune solids may be adjusted by the concentration, dilution, or both, of the water extract or extracts made. Such food may contain one or more of the optional acidifying ingredients specified in paragraph (b) (1) of this section, in a quantity sufficient to render the food slightly tart; it may contain honey added within the quantitative limits prescribed by paragraph (b) (2) of this section; and it may contain added vitamin C in a quantity prescribed by paragraph (b) (3) of this section. Such food is sealed in a container and so processed by heat, before or after sealing, as to prevent spoilage.

(b) The optional ingredients referred to in paragraph (a) of this section are:

(1) One or any combination of two or more of the following acidifying ingredients:

(i) Lemon juice.

(ii) Lime juice.

(iii) Citric acid.

(2) Honey, in a quantity not less than 2 percent and not more than 3 percent by weight of the finished food.

(3) Vitamin C, in a quantity such that the total vitamin C in each 6 fluid ounces of the finished food amounts to not less than 30 milligrams and not more than 50 milligrams.

(c) (1) The name of the food is "Prune juice—a water extract of dried prunes". For the purposes of the Federal Food, Drug, and Cosmetic Act concerning the label declaration of the name of the food, the explanatory statement "A water extract of dried prunes" may appear immediately below the words "prune juice", but there shall be no intervening written, printed, or graphic matter, and the type used for the words "A water extract of dried prunes" shall be of the same style and not less than half the print size of the type used for the words "prune juice".

(2) (i) When one or more of the acidifying ingredients specified in paragraph (b) (1) of this section are used, the label shall bear the statement "_____ added" or "with added _____", the blank being filled in with the name or names of the optional ingredients used.

(ii) When honey, as specified in paragraph (b) (2) of this section, is used the label shall bear the statement "with _____ honey" or "_____ honey added", the blank to be filled in with the percent by weight of the honey in the finished food or with the statement "between 2 and 3%".

(iii) When one or more of the ingredients designated in paragraph (b) (1) of this section and the ingredient designated in paragraph (b) (2) of this section are used, the statements specified in paragraph (c) (2) (i) and (ii) of this section may be combined, as for example, "with lemon juice and between 2 and 3% honey added".

(iv) When vitamin C is added as provided in paragraph (b) (3) of this section, it shall be designated on the label as "vitamin C added" or "with added vitamin C".

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words specified in this paragraph, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

PART 150—FRUIT BUTTERS, JELLIES, PRESERVES, AND RELATED PRODUCTS

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Fruit Butters, Jellies, Preserves, and Related Products

Sec.

150.110 Fruit butter.
150.140 Fruit jelly.
150.141 Artificially sweetened fruit jelly.
150.160 Fruit preserves and jams.
150.161 Artificially sweetened fruit preserves and jams.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046 as amended, 1055–1056 as amended (21 U.S.C. 341, 371).

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Fruit Butters, Jellies, Preserves, and Related Products

§ 150.110 Fruit butter.

(a) The fruit butters for which definitions and standards of identity are prescribed by this section are the smooth, semisolid foods each of which is made from a mixture of one or a permitted combination of the optional fruit ingredients specified in paragraph (b) of this section and one or any combination of the optional ingredients specified in paragraph (c) of this section, which meets the specifications in paragraph (d) of this section, and which is labeled in accordance with paragraph (e) of this section. Such mixture is concentrated with or without heat. The volatile flavoring materials or essence from such mixture may be captured during concentration, separately concentrated, and added back to any such mixture, together with any concentrated essence accompanying any optional fruit ingredient.

(b) (1) Each of the optional fruit ingredients referred to in paragraph (a) of this section is prepared by cooking one of the following fresh, frozen, canned, and/or dried (evaporated) mature fruits, with or without added water, and screening out skins, seeds, pits, and cores:

Name of fruit:	*Factor referred to in paragraph (d) (2) of this section*
Apple	7.5
Apricot	7.0
Grape	7.0
Peach	8.5
Pear	6.5
Plum (other than prune)	7.0
Prune	7.0
Quince	7.5

(2) The permitted combinations are of two, three, four, and five of the fruit ingredients specified in paragraph (b) (1) of this section; the weight of each is not less than one-fifth of the weight of the combination. Each such fruit ingredient in any such combination is an optional ingredient.

(c) The following safe and suitable optional ingredients may be used:

(1) Nutritive carbohydrate sweeteners.

(2) Spice.

(3) Flavoring (other than artificial flavoring).

(4) Salt.

(5) Acidifying agents.

(6) Fruit juice or diluted fruit juice or concentrated fruit juice, in a quantity not less than one-half the weight of the optional fruit ingredient.

(7) Preservatives.

(8) Antifoaming agents except those derived from animal fats.

(9) Pectin, in a quantity which reasonably compensates for deficiency, if any, of the natural pectin content of the fruit ingredient.

(d) For the purposes of this section:

(1) The mixture referred to in paragraph (a) of this section shall contain not less than five parts by weight of the fruit ingredient as measured in accordance with paragraph (d) (2) of this section to each two parts by weight of nutritive carbohydrate sweetener as measured in accordance with paragraph (d) (4) of this section.

(2) Any requirement with respect to the weight of any optional fruit ingredient, whether concentrated, unconcentrated, or diluted, means the weight determined by the following method: (i) Determine the percent of soluble solids in the optional fruit ingredient by the method for soluble solids referred to in paragraph (d) (3) of this section; (ii) multiply the percent so found by the weight of such fruit ingredient; (iii) divide the result by 100; (iv) subtract from the quotient the weight of any nutritive sweetener solids or other added solids; and (v) multiply the remainder by the factor for such ingredient prescribed in paragraph (b) (1) of this section. The result is the weight of the optional fruit ingredient.

(3) The soluble solids content of the finished fruit butter is not less than 43 percent, as determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed. 1975, p. 397, sec. 22.024, under "Soluble Solids (by Refractometer) in Fresh and Canned Fruits, Fruit Jellies, Marmalades, and Preserves—Official First Action," except that no correction is made for water-insoluble solids.

(4) The weight of any nutritive carbohydrate sweetener means the weight of the solids of such ingredient.

(5) The weight of fruit juice or diluted fruit juice or concentrated fruit juice (optional ingredient, paragraph (c) (6)) from a fruit specified in paragraph (b) (1) of this section is the weight of such juice, as determined by the method prescribed in paragraph (d) (2) of this section, except that the percent of soluble solids is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed., 1975, p. 566, sec. 31.011, under "Solids by Means of Refractometer—Official Final Action"; the weight of diluted concentrated juice from any other fruit is the original weight of the juice before it was diluted or concentrated.

(e) (1) The name of each fruit butter for which a definition and standard of identity is prescribed by this section is as follows:

(i) In case the fruit butter is made from a single fruit ingredient, the name is "Butter", preceded by the name where by such fruit is designated in paragraph (b) (1) of this section.

(ii) In case the fruit butter is made from a combination of two, three, four, or five fruit ingredients, the name is "Butter", preceded by the words "Mixed fruit" or by the names whereby such fruits are designated in paragraph (b) (1) of this section, in the order of predominance, if any, of the weight of such fruit ingredients in the combination.

(2) Each of the optional ingredients specified in paragraphs (b) and (c) of this section shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that:

(i) Other than in the case of dried (evaporated) fruit the name(s) of the fruit or fruits used may be declared without specifying the particular form of the fruit or fruits used. When the optional fruit ingredient is prepared in whole or in part from dried fruit, the label shall bear the words "prepared from" or "prepared in part from", as the case may be, followed by the word "evaporated" or "dried", followed by the name whereby such fruit is designated in paragraph (c) of this section. When two or more such optional fruit ingredients are used, such names, each preceded by the word "evaporated" or "dried", shall appear in the order of predominance, if any, of the weight of such ingredients in the combination.

(ii) If sugar or invert sugar is the sweetener used, the term "sugar" may be used, and if the sweetener used is derived from corn the term "corn sweetener" may be used.

§ 150.140 Fruit jelly.

(a) The jellies for which definitions and standards of identity are prescribed by this section are the jelled foods each of which is made from a mixture of one or a permitted combination of the fruit juice ingredients specified in paragraph (b) of this section and one or any combination of the optional ingredients specified in paragraph (c) of this section, which meets the specifications in paragraph (d) of this section and which is labeled in accordance with paragraph (e) of this section. Such mixture is concentrated with or without heat. The volatile flavoring materials or essence from such mixture may be captured during concentration, separately concentrated, and added back to any such mixture, together with any concentrated essence accompanying any optional fruit ingredient.

(b)(1) Each of the fruit juice ingredients referred to in paragraph (a) of this section is the filtered or strained liquid extracted with or without the application of heat and with or without the addition of water, from one of the following mature, properly prepared fruits which are fresh, frozen and/or canned:

Name of fruit:	*Factor referred to in paragraph (d)(2) of this section*
Apple	7.5
Apricot	7.0
Blackberry (other than dewberry)	10.0
Black raspberry	9.0
Boysenberry	10.0
Cherry	7.0
Crabapple	6.5
Cranberry	9.5
Damson, damson plum	7.0
Dewberry (other than boysenberry, loganberry, and youngberry)	10.0
Fig	5.5
Gooseberry	12.0
Grape	7.0
Grapefruit	11.0
Greengage, greengage plum	7.0
Guava	13.0
Loganberry	9.5
Orange	8.0
Peach	8.5
Pineapple	7.0
Plum (other than damson, greengage, and prune)	7.0
Pomegranate	5.5
Prickly pear	11.0
Quince	7.5
Raspberry, red raspberry	9.5
Red currant, currant (other than black currant)	9.5
Strawberry	12.5
Youngberry	10.0

(2) The permitted combinations are of two, three, four, or five of the fruit juice ingredients specified in paragraph (b)(1) of this section, the weight of each is not less than one-fifth of the weight of the combination. Each such fruit juice ingredient in any such combination is an optional ingredient.

(c) The following safe and suitable optional ingredients may be used:

(1) Nutritive carbohydrate sweeteners.

(2) Spice.

(3) Acidifying agents.

(4) Pectin, in a quantity which reasonably compensates for deficiency, if any, of the natural pectin content of the fruit juice ingredient.

(5) Buffering agents.

(6) Preservatives.

(7) Antifoaming agents except those derived from animal fats.

(8) Mint flavoring and artificial green coloring, in case the fruit juice ingredient or combination of fruit juice ingredients is extracted from apple, crabapple, pineapple, or two or all of such fruits.

(9) Cinnamon flavoring, other than artificial flavoring, and artificial red coloring in case the fruit juice ingredient or combination of fruit juice ingredients is extracted from apple or crabapple or both such fruits.

(d) For the purposes of this section:

(1) The mixture referred to in paragraph (a) of this section shall contain not less than 45 parts by weight of the fruit juice ingredients as measured in accordance with paragraph (d)(2) of this section to each 55 parts by weight of saccharine ingredient as measured in accordance with paragraph (d)(4) of this section.

(2) Any requirement with respect to the weight of any fruit juice ingredient, whether prepared from concentrated, unconcentrated, or diluted fruit juice means the weight determined by the following method: (i) Determine the percent of soluble solids in such fruit juice ingredient by the method for soluble solids referred to in paragraph (d)(3) of this section; (ii) multiply the percent so found by the weight of such fruit juice ingredient; (iii) divide the result by 100; (iv) subtract from the quotient the weight of any added saccharine ingredient solids or other added solids; and (v) multiply the remainder by the factor for such fruit juice ingredient prescribed in paragraph (b) of this section. The result is the weight of the fruit juice ingredient.

(3) The soluble-solids content of the finished jelly is not less than 65 percent, as determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970) p. 526, Sec. 31.011, "Solids By Means of Refractometer—Official Final Action."[3]

(4) The weight of any optional saccharine ingredient means the weight of the solids of such ingredient.

(e)(1) The name of each jelly for which a definition and standard of identity is prescribed by this section is as follows:

(i) In case the jelly is made with a single fruit juice ingredient, the name is "Jelly", preceded or followed by the name or synonym whereby the fruit from which such fruit juice ingredient was extracted is designated in paragraph (b) of this section.

(ii) In case the jelly is made with a combination of two, three, four, or five fruit juice ingredients, the name is "Jelly", preceded or followed by the words "Mixed fruit" or by the names or synonyms whereby the fruits from which the fruit juice ingredients were extracted are designated in paragraph (b) of this section, in the order of predominance, if any, of the weights of any such fruit juice ingredients in the combination.

(2) Each of the optional ingredients specified in paragraphs (b) and (c) of this section shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that:

(i) The name(s) of the fruit or fruits used may be declared without specifying the particular form of the fruit or fruits used.

(ii) When the optional ingredients listed in paragraph (c) (3), (4), and (5) of this section are declared on the label, the declaration may be followed by the statement "Used as needed" on all jellies to which they are customarily, but not always, added to compensate for natural variations in the fruit juice ingredients used.

§ 150.141 Artificially sweetened fruit jelly.

(a) The artificially sweetened fruit jellies for which definitions and standards of identity are prescribed by this section are the jellied foods made from a fruit juice ingredient as specified in paragraph (b) of this section and an artificial sweetening ingredient as specified in paragraph (c) of this section, with a jelling ingredient as specified in paragraph (d) of this section. Water may be added. The quantity of the fruit juice ingredient, calculated as set out in § 150.140(b), amounts to not less than 55 percent by weight of the finished food. The article is sealed in containers and so processed by heat, either before or after sealing, as to prevent spoilage. Such food may also contain one or more of the following optional ingredients:

(1) Spice, spice oil, spice extract.

(2) A vinegar, lemon juice, lime juice, citric acid, lactic acid, malic acid, tartaric acid, fumaric acid, or any combination of two or more of these, in a quantity which reasonably compensates for de-

[3] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

ficiency, if any, of the natural acidity of the fruit juice ingredient.

(3) Sodium citrate, sodium acetate, sodium tartrate, monosodium phosphate, disodium phosphate, trisodium phosphate, sodium potassium tartrate, potassium citrate, potassium acid tartrate, or any combination thereof, in an amount not exceeding 2 ounces avoirdupois per 100 pounds of the finished food.

(4) Sodium hexametaphosphate in an amount not exceeding 8 ounces avoirdupois per 100 pounds of the finished food.

(5) Purified calcium chloride, calcium citrate, calcium gluconate, calcium lactate, calcium sulfate, monocalcium phosphate, potassium chloride, or any combination of two or more of these salts, in a quantity reasonably necessary to enable the jelling ingredients to produce a jellied finished product.

(6) Ascorbic acid, sorbic acid, sodium sorbate, potassium sorbate, sodium propionate, calcium propionate, sodium benzoate, benzoic acid, methylparaben (methyl-*p*-hydroxybenzoate), propylparaben (propyl-*p*-hydroxybenzoate), or any combination of two or more of these, in a quantity reasonably necessary as a preservative, but not to exceed 0.1 percent by weight of the finished food.

(b) The fruit juice ingredient referred to in paragraph (a) of this section is any one, or any combination of two, three, four, or five of the fruit juice ingredients complying with the requirements of § 150.140(c). Except as paragraph (d) of this section permits the use of pectin, carrageenan, or salts of carrageenan standardized with nutritive sweetener, no nutritive sweetening ingredient is added, either directly or indirectly, to the fruit juice ingredient used to make artificially sweetened fruit jelly.

(c) The artificial sweetening ingredients referred to in paragraph (a) of this section are saccharin, sodium saccharin, calcium saccharin, or any combination of two or more of these.

(d) The jelling ingredients referred to in paragraph (a) of this section are pectin, agar-agar, carob bean gum (also called locust bean gum), guar gum, gum karaya, gum tragacanth, algin (sodium alginate), sodium carboxymethylcellulose (cellulose gum), methylcellulose (meeting U.S.P. requirements and with methoxy content not less than 27.5 percent and not more than 31.5 percent on a dry-weight basis), carrageenan or salts of carrageenan complying with the requirements of § 172.620 or § 172.626 of this chapter, or any combination of two or more of these. Pectin may be standardized with a nutritive sweetening ingredient, but such sweetening ingredient shall not amount to more than 44 percent by weight of the standardized pectin and the quantity of such standardized pectin used shall not exceed 3 percent by weight of the finished food. Carrageenan or salts of carrageenan may be standardized with a nutritive sweetening ingredient, but such sweetening ingredient shall not amount to more than 25 percent by weight of the standardized carrageenan or salts of carrageenan and the quantity of such standardized carrageenan or salts of carrageenan used shall not exceed 2 percent by weight of the finished food.

(e) The name of each artificially sweetened fruit jelly for which a definition and standard of identity is prescribed by this section consists of the words "artifically sweetened", immediately followed by the name prescribed by § 150.140(e)(1) for the fruit jelly which corresponds in its fruit ingredient to the artificially sweetened article. The words "artificially sweetened" shall be prominently and conspicuously displayed in letters not smaller than the largest letter used in any other word in the name of the food.

(f)(1) The jelling ingredient used shall be named on the label by a statement "_____added" or "with added _____", the blank being filled in with the common name of the jelling ingredient used; for example, "pectin and methylcellulose added".

(2) When one of the optional ingredients specified in paragraph (a)(1) of this section is used, the label shall bear the statement "_____ added" or "with added _____", the blank being filled in with the words "spice", "spice oil", or "spice extract" as appropriate, but in lieu of the word "spice" in such statement the common name of the spice may be used.

(3) When the optional ingredient specified in paragraph (a)(4) of this section is used, the label shall bear the words "sodium hexametaphosphate added" or "with added sodium hexametaphosphate".

(4) When any optional ingredient listed in paragraph (a)(6) of this section is used, the label shall bear the statement "_____ added as a preservative", the blank being filled in with the common name of the preservative ingredient used as designated in paragraph (a)(6) of this section.

(g) Wherever the name of the food appears on the label of the artificially sweetened fruit jelly so conspicuously as to be easily seen under customary conditions of purchase, the words and statements specified in this section, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter, except that the varietal name of the fruit source of the fruit juice ingredient used in preparing such jelly may so intervene.

§ 150.160 Fruit preserves and jams.

(a) The preserves or jams for which definitions and standards of identity are prescribed by this section are the viscous or semi-solid foods, each of which is made from a mixture composed of one or a permitted combination of the fruit ingredients specified in paragraph (b) of this section and one or any combination of the optional ingredients specified in paragraph (c) of this section which meets the specifications in paragraph (d) of this section, and which is labeled in accordance with paragraph (e) of this section. Such mixture, with or without added water, is concentrated with or without heat. The volatile flavoring material from such mixture may be captured during concentration, separately concentrated, and added back to any such mixture, together with any concentrated essence accompanying any optional fruit ingredient.

(b)(1) The fruit ingredients referred to in paragraph (a) of this section are the following mature, properly prepared fruits which are fresh, concentrated, frozen and/or canned:

Group I

Blackberry (other than dewberry)	Grapefruit
Black raspberry	Huckleberry
Blueberry	Loganberry
Boysenberry	Orange
Cherry	Pineapple
Crabapple	Raspberry, red raspberry
Dewberry (other than boysenberry, loganberry, and youngberry)	Rhubarb
Elderberry	Strawberry
Grape	Tangerine
	Tomato
	Yellow tomato
	Youngberry

Group II

Apricot	Nectarine
Cranberry	Peach
Damson, damson plum	Pear
Fig	Plum (other than greengage plum and damson plum)
Gooseberry	Quince
Greengage, greengage plum	Red currant, currant (other than black currant)
Guava	

(2) The following combinations of fruit ingredients may be used:

(i) Any combination of two, three, four, or five of such fruits in which the weight of each is not less than one-fifth of the weight of the combination; except that the weight of pineapple may be not less than one-tenth of the weight of the combination.

(ii) Any combination of apple and one, two, three, or four of such fruits in which the weight of each is not less than one-fifth and the weight of apple is not more than one-half of the weight of the combination; except that the weight of pineapple may be not less than one-tenth of the weight of the combination.

In any combination of two, three, four, or five fruits, each such fruit is an optional ingredient. For the purposes of this section the word "fruit" includes the vegetables specified in this paragraph.

(c) The following safe and suitable optional ingredients may be used:

(1) Nutritive carbohydrate sweeteners.

(2) Spice.

(3) Acidifying agents.

(4) Pectin, in a quantity which reasonably compensates for deficiency, if any, of the natural pectin content of the fruit ingredient.

(5) Buffering agents.

(6) Preservatives.

(7) Antifoaming agents, except those derived from animal fat.

(d) For the purposes of this section:

(1) The mixture referred to in paragraph (a) of this section shall be composed of not less than: (i) In the case of a fruit ingredient consisting of a Group I fruit or a permitted combination exclusively of Group I fruits, 47 parts by weight of the fruit ingredient to each 55 parts by weight of the saccharine ingre-

dient; and (ii) in all other cases, 45 parts by weight of the fruit ingredient to each 55 parts by weight of the saccharine ingredient. The weight of the fruit ingredient shall be determined in accordance with paragraph (d)(2) of this section, and the weight of the saccharine ingredient shall be determined in accordance with paragraph (d)(5) of this section.

(2) Any requirement with respect to the weight of any fruit, combination of fruits, or fruit ingredient means:

(i) The weight of fruit exclusive of the weight of any sugar, water, or other substance added for any processing or packing or canning, or otherwise added to such fruit.

(ii) In the case of fruit prepared by the removal, in whole or in part, of pits, seeds, skins, cores, or other parts; the weight of such fruit, exclusive of the weight of all such substances removed therefrom.

(iii) In the cases of apricots, cherries, grapes, nectarines, peaches, and all varieties of plums, whether or not pits and seeds are removed therefrom; the weight of such fruit, exclusive of the weight of such pits and seeds.

(iv) In the case of concentrated fruit, the weight of the properly prepared fresh fruit used to produce such concentrated fruit.

(3) The term "concentrated fruit" means a concentrate made from the properly prepared edible portion of mature fresh or frozen fruits by removal of moisture with or without the use of heat or vacuum, but not to the point of drying. Such concentrate is canned or frozen without the addition of sugar or other sweetening agents and is identified to show or permit the calculation of the weight of the properly prepared fresh fruit used to produce any given quantity of such concentrate. The volatile flavoring material or essence from such fruits may be captured during concentration and separately concentrated for subsequent addition to the concentrated fruit either directly or during manufacture of the preserve or jam, in the original proportions present in the fruit.

(4) The weight of any optional saccharine ingredient means the weight of the solids of such ingredient.

(5) The soluble-solids content of the finished jam or preserve is not less than 65 percent, as determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed. (1970) p. 371, Sec. 22.019, "Soluble Solids (By Refractometer) in Fresh and Canned Fruits, Jams, Marmalades, and Preserves—Official First Action,"[2] except that no correction is made for water-insoluble solids.

(e)(1) The name of each preserve or jam for which a definition and standard of identity is prescribed by this section is as follows:

(i) If the fruit ingredient is a single fruit, the name is "Preserve" or "Jam", preceded or followed by the name or synonym whereby such fruit is designated in paragraph (b) of this section.

(ii) If the fruit ingredient is a combination of two, three, four, or five fruits, the name is "Preserve" or "Jam", preceded or followed by the words "Mixed fruit" or by the names or synonyms whereby such fruits are designated in paragraph (b) of this section, in the order of predominance, if any, of the weights of such fruits in the combination.

(2) Each of the optional ingredients specified in paragraphs (b) and (c) of this section shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that:

(i) The name(s) of the fruit or fruits used may be declared without specifying the particular form of the fruit or fruits used.

(ii) When the optional ingredients listed in paragraph (c) (3), (4), and (5) of this section are declared on the label, the declaration may be followed by the statement "used as needed" on all preserves or jams to which they are customarily, but not always, added to compensate for natural variations in the fruit ingredients used.

§ 150.161 Artificially sweetened fruit preserves and jams.

(a) The artificially sweetened fruit preserves or artificially sweetened fruit jams for which definitions and standards of identity are prescribed by this section are the viscous or semisolid foods made from a fruit ingredient as specified in paragraph (b) of this section and an artificial sweetening ingredient as specified in paragraph (c) of this section, and with or without water and a jelling ingredient as specified in paragraph (d) of this section. The quantity of the fruit ingredient amounts to not less than 55 percent by weight of the finished food. The article is sealed in containers and so processed by heat, either before or after sealing, as to prevent spoilage. Such food may also contain one or more of the following optional ingredients:

(1) Spice, spice oil, spice extract.

(2) A vinegar, lemon juice, lime juice, citric acid, lactic acid, malic acid, tartaric acid, fumaric acid, or any combination of two or more of these, in a quantity which reasonably compensates for deficiency, if any, of the natural acidity of the fruit ingredient.

(3) Sodium citrate, sodium acetate, sodium tartrate, monosodium phosphate, disodium phosphate, trisodium phosphate, sodium potassium tartrate, potassium citrate, potassium acid tartrate, or any combination thereof, in an amount not exceeding 2 ounces avoirdupois per 100 pounds of the finished food.

(4) Sodium hexametaphosphate in an amount not exceeding 8 ounces avoirdupois per 100 pounds of the finished food.

(5) Purified calcium chloride, calcium citrate, calcium gluconate, calcium lactate, calcium sulfate, monocalcium phosphate, potassium chloride, or any combination of two or more of these salts, in a quantity reasonably necessary to enable the jelling ingredients to produce a jelled finished product.

(6) Ascorbic acid, sorbic acid, sodium sorbate, potassium sorbate, sodium propionate, calcium propionate, sodium benzoate, benzoic acid, methylparaben (methyl-*p*-hydroxybenzoate), propylparaben (propyl-*p*-hydroxybenzoate), or any combination of two or more of these, in a quantity reasonably necessary as a preservative but not to exceed 0.1 percent by weight of the finished food.

(b) The fruit ingredient referred to in paragraph (a) of this section is any one, or any combination of two, three, four, or five of the fruit ingredients complying with the requirements of § 150.160(b) and (c). Except as paragraph (d) of this section permits the use of pectin, carrageenan, or salts of carrrageenan standardized with nutritive sweetener, no nutritive sweetening ingredient is added, either directly or indirectly, to the fruit ingredient used to make artificially sweetened fruit preserves or artificially sweetened fruit jam.

(c) The artificial sweetening ingredients referred to in paragraph (a) of this section are saccharin, sodium saccharin, calcium saccharin, or any combination of two or more of these.

(d) The jelling ingredients referred to in paragraph (a) of this section are pectin, agar-agar, carob bean gum (also called locust bean gum), guar gum, gum karaya, gum tragacanth, algin (sodium alginate), sodium carboxymethylcellulose (cellulose gum), methylcellulose (meeting U.S.P. requirements and with methoxy content not less than 27.5 percent and not more than 31.5 percent on a dry-weight basis), carrageenan or salts of carrageenan complying with the requirements of § 172.620 or § 172.626 of this chapter, or any combination of two or more of these. Pectin may be standardized with a nutritive sweetening ingredient, but such sweetening ingredient shall not amount to more than 44 percent by weight of the standardized pectin and the quantity of such standardized pectin used shall not exceed 3 percent by weight of the finished food. Carrageenan or salts of carrageenan may be standardized with a nutritive sweetening ingredient, but such sweetening ingredient shall not amount to more than 25 percent by weight of the standardized carrageenan or salts of carrageenan and the quantity of such standardized carrageenan or salts of carrageenan used shall not exceed 2 percent by weight of the finished food.

(e) The name of each artificially sweetened fruit preserve or artificially sweetened fruit jam for which a definition and standard of identity is prescribed by this section consists of the words "artificially sweetened" immediately followed by the name prescribed by § 150.160(e)(1) for the fruit preserves or jams which correspond in fruit ingredient to the artificially sweetened article. The words "artificially sweetened" shall be prominently and conspicuously displayed in letters not smaller than the largest letter used in any other word in the name of the food.

[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

(f) (1) The jelling ingredient used shall be named on the label by a statement "_____ added" or "with added _____", the blank being filled in with the common name of the jelling ingredient used.

(2) When one of the optional ingredients specified in paragraph (a) (1) of this section is used, the label shall bear the statement, "_____ added" or "with added _____", the blank being filled in with the words "spice", "spice oil", or "spice extract" as appropriate, but in lieu of the word "spice" in such statement the common name of the spice may be used.

(3) When the optional ingredient specified in paragraph (a) (4) of this section is used, the label shall bear the words "sodium hexametaphosphate added" or "with added sodium hexametaphosphate".

(4) When any optional ingredient listed in paragraph (a) (6) of this section is used, the label shall bear the statement "_____ added as a preservative", the blank being filled in with the common name by which the preservative ingredient used is designated in paragraph (a) (6) of this section.

(g) Wherever the name of the food appears on the label of the artificially sweetened fruit preserve or artificially sweetened fruit jam so conspicuously as to be easily seen under customary conditions of purchase, the words and statements specified in this section, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter, except that the varietal name of the fruit used in preparing such preserve or jam may so intervene.

PART 152—FRUIT PIES

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Fruit Pies

Sec.

152.126 Frozen cherry pie.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046 as amended, 1055–1056 as amended (21 U.S.C. 341, 371).

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Fruit Pies

§ 152.126 Frozen cherry pie.

(a) *Identity*—(1) Frozen cherry pie (excluding baked and then frozen) is the food prepared by incorporating in a filling contained in a pastry shell mature, pitted, stemmed cherries that are fresh, frozen, and/or canned. The top of the pie may be open or it may be wholly or partly covered with pastry or other suitable topping. Filling, pastry, and topping components of the food consist of optional ingredients as prescribed by paragraph (a) (2) of this section. The finished food is frozen.

(2) The optional ingredients referred to in paragraph (a) (1) of this section consist of suitable substances that are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act or color additives as defined in section 201(t) of the act; or if they are food additives or color additives as so defined, they are used in conformity with regulations established pursuant to section 409 or 706 of the act. Ingredients that perform a useful function in the formulation of the filling, pastry, and topping components, when used in amounts reasonably required to accomplish their intended effect, are regarded as suitable except that artificial sweeteners are not suitable ingredients of frozen cherry pie.

(3) The name of the food for which a definition and standard of identity is established by this section is frozen cherry pie; however, if the maximum diameter of the food (measured across opposite outside edges of the pastry shell) is not more than 4 inches, the food alternatively may be designated by the name frozen cherry tart. The word "frozen" may be omitted from the name on the label if such omission is not misleading.

(4) (i) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(ii) The label shall not bear any misleading pictorial representation of the cherries in the pie.

(b) *Quality*—(1) The standard of quality for frozen cherry pie is as follows:

(i) The fruit content of the pie is such that the weight of the washed and drained cherry content is not less than 25 percent of the weight of the pie when determined by the procedure prescribed by paragraph (b) (2) of this section.

(ii) Not more than 15 percent by count of the cherries in the pie are blemished with scab, hail injury, discoloration, scar tissue, or other abnormality. A cherry showing skin discoloration (other than scald) having an aggregate area exceeding that of a circle nine thirty-seconds of an inch in diameter is considered to be blemished. A cherry showing discoloration of any area but extending into the fruit tissue is also considered to be blemished.

(2) Compliance with the requirement for the weight of the washed and drained cherry content of the pie, as prescribed by paragraph (b) (1) (i) of this section, is determined by the following procedure:

(i) Select a random sample from a lot:

(*a*) At least 24 containers if they bear a weight declaration of 16 ounces or less.

(*b*) Enough containers to provide a total quantity of declared weight of at least 24 pounds if they bear a weight declaration of more than 16 ounces.

(ii) Determine net weight of each frozen pie.

(iii) Temper the pie until the top crust can be removed.

(iv) Remove the filling and cherries from the pie and transfer to the surface of a previously weighed 12-inch diameter U.S. No. 8 sieve (0.094-inch openings) stacked on a U.S. No. 20 sieve (0.033-inch openings).

(v) Distribute evenly over the surface and wash with a gentle spray of water at 70°–75° F to free the cherries and cherry fragments from the adhering material.

(vi) Remove the U.S. No. 8 sieve and examine the U.S. No. 20 sieve and transfer all cherry fragments to the U.S. No. 8 sieve.

(vii) Drain the cherry contents on the No. 8 sieve for 2 minutes in an inclined position (15°–30° slope). Weigh the U.S. No. 8 sieve and the washed and drained cherries to the nearest 0.01 ounce.

(viii) The weight of the washed and drained cherries is the weight of the sieve and the cherry material less the weight of the sieve. Calculate the percent of the cherry content of each pie with the following formula, and then calculate the average percent of the entire random sample:

$$\text{Percent of the cherry content of the pie} = \frac{\text{Weight of washed and drained cherries}}{\text{Net weight of pie}} \times 100.$$

(3) If the quality of the frozen cherry pie falls below the standard of quality prescribed by paragraph (b) (1) of this section, the label shall bear the general statement of substandard quality specified in § 130.14(a) of this chapter, in the manner and form specified therein; but in lieu of the words prescribed for the second line inside the rectangle, the label may bear the alternative statement "Below standard in quality _____", the blank being filled in with the following words, as applicable: "too few cherries", or "blemished cherries". Such alternative statement shall immediately and conspicuously precede or follow, without intervening written, printed, or graphic matter, the name of the food as prescribed by paragraph (a) of this section.

PART 155—CANNED VEGETABLES

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Canned Vegetables

Sec.

155.120 Canned green beans and canned wax beans.
155.130 Canned corn.
155.131 Canned field corn.
155.170 Canned peas.
155.172 Canned dry peas.
155.190 Canned tomatoes.
155.191 Tomato paste.
155.192 Tomato puree.
155.194 Catsup.
155.200 Certain other canned vegetables.
155.201 Canned mushrooms.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046 as amended, 1055–1056 as amended (21 U.S.C. 341, 371) unless otherwise indicated.

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Canned Vegetables

§ 155.120 Canned green beans and canned wax beans.

(a) *Identity*—(1) *Definition.* Canned green beans and canned wax beans are the foods prepared from succulent pods of fresh green bean or wax bean plants conforming to the characteristics of *Phaseolus vulgaris* L. *and Phaseolus coccineus* L. The optional color and varietal types and styles of the bean ingredient are set forth in paragraph (a) (2) of this section. The product is packed with water or other suitable aqueous liquid medium to which may be added one or more of the other optional ingredients set forth in paragraph (a) (3) of this section. Such food is so processed by heat, in an appropriate manner before or after being sealed in a container, as to prevent spoilage.

(2) *Optional color and varietal types and styles of pack.* The optional color and varietal types and styles of the bean ingredient referred to in paragraph (a) (1) of this section are:

(i) *Optional color types.* The beans shall be one of the following distinct color types: (*a*) Green; or (*b*) Wax.

(ii) *Optional varietal types*—(*a*) *Round.* Beans having a width not greater than 1½ times the thickness of the bean; or

(*b*) *Flat.* Beans having a width greater than 1½ times the thickness of the bean.

(iii) *Optional styles of pack*—(*a*) *Whole.* Whole pods of any length.

(*b*) *Shoestring or sliced lengthwise or French style.* Pods sliced lengthwise or at an angle of less than 45° to the longitudinal axis.

(*c*) *Cuts.* Transversely cut pods not less than 19 mm (0.75 in) long as measured along the longitudinal axis, which may contain the shorter end pieces that result from cutting such pods.

(*d*) *Short cuts.* Pieces of pods cut transversely of which 75 percent, by count, or more are less than 19 mm (0.75 in) in length and not more than 1 percent by count are more than 32 mm (1¼ in) in length.

(*e*) *Diagonal cuts.* Pods cut in lengths as specified in paragraph (a) (2) (iii) (*c*) of this section, except the pods are cut at an angle approximately 45° to the longitudinal axis.

(*f*) *Diagonal short cuts.* Pods cut in lengths as specified in paragraph (a) (2) (iii) (*d*) of this section, except the pods are cut at an angle approximately 45° to the longitudinal axis.

(*g*) *Mixture.* Any mixture of two or more of the styles specified in paragraph (a) (2) (iii) (*a*) to (*f*), inclusive, of this section.

(3) *Optional ingredients.* In addition to the optional packing media listed in paragraph (a) (1) of this section and the optional types and styles of beans ingredient listed in paragraph (a) (2) of this section, the following safe and suitable optional ingredients may be used:

(i) Salt.

(ii) Monosodium glutamate.

(iii) Disodium inosinate.

(iv) Disodium guanylate.

(v) Hydrolyzed vegetable protein.

(vi) Autolyzed yeast extract.

(vii) Nutritive carbohydrate sweeteners.

(viii) Spice.

(ix) Flavoring (except artificial).

(x) Pieces of green or red peppers or mixtures of both, either of which may be dried, or other vegetables not exceeding in total 15 percent by weight of the finished product.

(xi) Vinegar.

(xii) Lemon juice or concentrated lemon juice.

(xiii) Mint leaves.

(xiv) Butter or margarine in a quantity of not less than 3 percent by weight of the finished product. When butter or margarine is added, emulsifiers or stabilizers, or both, may be added. No spice or flavoring simulating the color or flavor imparted by butter or margarine is used.

(4) *Labeling*—(i) The name of the food is "green beans" or " wax beans" as appropriate. Wax beans may be additionally designated "golden" or "yellow".

(ii) The following shall be included as part of the name or in conjunction with the name of the food:

(*a*) A declaration of any flavoring that characterizes the product, as specified in § 101.22 of this chapter.

(*b*) A declaration of any spice, seasoning, or garnishing that characterizes the product, e.g., "with added spice", or, in lieu of the word spice, the common name of the spice, e.g., "seasoned with green peppers".

(*c*) The name of the optional style of pack of bean ingredient as set forth in paragraph (a) (2) (iii) of this section or, if a product consists of a mixture of such styles, the words "mixture of ------", the blank to be filled in with the names of the styles present, arranged in the order of decreasing predominance, if any, by weight of such ingredients. If the product consists of whole beans and the pods are packed parallel to the sides of the container, the word "whole" may be preceded or followed by the words "vertical pack", or if the pods are cut at both ends and are of substantially equal lengths, the words "asparagus style" may be used in lieu of the words "vertical pack". If the product consists of "short cuts" or "diagonal short cuts" a numerical expression indicating the predominate length of cut in the finished food may be used in lieu of the word "short", e.g., "½ inch cut".

(iii) The following may be included in the name of the food:

(*a*) The word "stringless" where the beans are in fact stringless.

(*b*) The name of the optional varietal type as specified in paragraph (a) (2) (ii) of this section.

(iv) If a term designating diameter is used, it shall be supported by an exact graphic representation of the cross section of the bean pod or by a statement of the maximum diameter in common or decimal fractions of an inch and, optionally, by the millimeter equivalent stated parenthetically. The diameter of a whole, cut, diagonal cut, or short cut is determined by measuring the thickest portion of the pod at the shorter diameter of the bean perpendicular to the longitudinal axis.

(5) *Ingredient statement.* The name of each optional ingredient used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(b) *Quality*—(1) When tested by the method prescribed in paragraph (b) (2) of this section:

(i) In the case of cut beans and diagonal cut beans under paragraph (a) (2) (iii) (*c*) and (*d*) of this section and mixtures of two or more optional forms under paragraph (a) (2) (iii) (*g*) of this section, not more than 60 units per 340 g (12 oz) drained weight are less than 13 mm (0.50 in) long: *Provided,* That where the number of units per 340 g (12 oz) drained weight exceeds 240, not more than 25 percent by count of the total units are less than 13 mm (0.50 in) long.

(ii) Not more than 5 percent by weight of the units may possess strings that will support the weight of 250 g (8.8 oz) for 5 seconds or longer.

(iii) The deseeded pods contain not more than 0.15 percent by weight of fibrous material.

(iv) There are not more than 10 percent by weight of blemished units of which amount not more than one-half may be materially damaged by insect or pathological injury. A unit is considered blemished when the aggregate blemished area exceeds the area of a circle 3 mm (⅛ in) in diameter. Materially damaged means that the unit is damaged to the extent that the appearance or eating quality of the unit is seriously affected.

(v) There are not more than 8 unstemmed units per 340 g (12 oz) drained weight.

(vi) The combined number of leaves, detached stems, and other extraneous vegetable matter shall not average more than 3 pieces per 340 g (12 oz) drained beans.

(2) Canned beans shall be tested by the following method to determine whether they meet the requirements of paragraph (b) (1) of this section:

(i) Distribute the contents of the container over the meshes of a U.S. No. 8 circular sieve with openings of 2.36 mm (0.0937 in) which has been previously weighed. The diameter of the sieve is 20.3 cm (8 in) if the quantity of the contents of the container is less than 1.36 kg (3 lb) and 30.5 cm (12 in) if such quantity is 1.36 kg (3 lb) or more. The bottom of the sieve is woven-wire cloth which complies with the specifications for such cloth set forth in the "Definitions of Terms and Explanatory Notes," p. xviii, of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Edition, 1975. Without shifting the material on the sieve, incline the sieve 17 to 20 degrees to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and the drained material. Record in grams the weight so found, less the

weight of the sieve, as the drained weight.

(ii) Pour the drained material from the sieve into a flat tray and spread it in a layer of fairly uniform thickness. Count the total number for units. For the purpose of this count—loose seeds, pieces of seed, loose stems, and extraneous material are not to be included. Divide the number of units by the drained weight recorded in paragraph (b)(2)(i) of this section and multiply by 340 to obtain the number of units per 340 g (12 oz.) drained weight.

(iii) Examine the drained material in the tray, weigh and record weight of blemished units, count and record the number of unstemmed units; and, in case the material consists of the optional ingredient specified in paragraph (a)(2)(iii) (*c*), (*d*) or (*f*) of this section, count and record the number of units which are less than 13 mm (0.50 in.) long. If the number of units per 340 g (12 oz.) is 240 or less, divide the number of units which are less than 13 mm (0.50 in.) by the drained weight recorded in paragraph (b)(2)(i) of this section and multiply by 340 to obtain the number of such units per 340 g (12 oz.) drained weight. If the number of units per 340 g (12 oz.) exceeds 240, divide the number of units less than 13 mm (0.50 in.) long by the total number of units and multiply by 100 to determine the percentage by count of the total units which are less than 13 mm (0.50 in.) long.

(*a*) Divide the weight of blemished units by the drained weight recorded in paragraph (b)(2)(i) of this section and multiply by 100 to obtain the percentage by weight of blemished units in the container.

(*b*) Divide the number of unstemmed units by the drained weight recorded in paragraph (b)(2)(i) of this section and multiply by 340 to obtain the number of unstemmed units per 340 g (12 oz.) of drained weight.

(iv) Remove from the tray the extraneous vegetable material, count, record count, and return to tray.

(v) Remove from the tray one or more representative samples of 99 to 113 g (3½ to 4 ounces) covering each sample as taken to prevent evaporation.

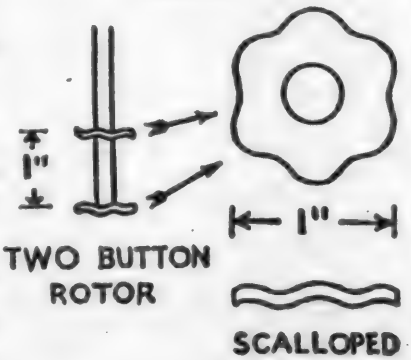
(vi) From each representative sample selected in paragraph (b)(2)(v) of this section, discard any loose seed and extraneous vegetable material and detach and discard any attached stems. Except with optional style of ingredient specified in paragraph (a)(2)(iii)(*b*) of this section (pods sliced lengthwise), trim off, as far as the end of the space formerly occupied by the seed, any portion of pods from which the seed has become separated. Remove and discard any portions of seed from the trimmings and reserve the trimmings for paragraph (b)(2)(viii) of this section. Weigh and record the weight of the trimmed pods. Deseed the trimmed pods and reserve the deseeded pods for paragraph (b)(2)(viii) of this section. Remove strings from the pods during the deseeding operation. Reserve these strings for testing as prescribed in paragraph (b)(2)(vii) of this section. In the case of pods sliced lengthwise, remove seed and pieces of seed and reserve the deseeded pods for use as prescribed in paragraph (b)(2)(viii) of this section.

(vii) If strings have been removed for testing, as prescribed in paragraph (b)(2)(vi) of this section, test them as follows:

Fasten clamp, weighted to 250 g (8.8 oz.), to one end of the string, grasp the other end with the fingers (a cloth may be used to aid in holding the string), and lift gently. Count the string as tough if it supports the 250 g (8.8 oz.) weight for at least 5 seconds. If the string breaks before 5 seconds, test such parts into which it breaks as are 13 mm (½ in.) or more in length; and if any such part of the string supports the 250 g (8.8 oz.) weight for at least 5 seconds, count the string as tough. Divide the number of tough strings by the weight of the sample recorded in paragraph (b)(2)(v) of this section and multiply by 340 to obtain the number of tough strings per 340 g (12 oz.) drained weight.

(viii) Combine the deseeded pods with the trimmings reserved in paragraph (b)(2)(vi) of this section, and, if strings were tested as prescribed in paragraph (b)(2)(vii) of this section, add such strings broken or unbroken. Weigh and record weight of combined material. Transfer to the metal cup of a malted-milk stirrer and mash with a pestle. Wash material adhering to the pestle back into cup with 200 cc of boiling water. Bring mixture nearly to a boil, add 25 cc of 50 percent (by weight) sodium hydroxide solution and bring to a boil. (If foaming is excessive, 1 cc of capryl alcohol may be added.) Boil for 5 minutes, then stir for 5 minutes with a malted-milk stirrer capable of a no-load speed of at least 7,200 rpm. Use a rotor with two scalloped buttons shaped as shown in Exhibit 1 as follows:

EXHIBIT 1



Transfer the material from the cup to a previously weighed 30-mesh monel metal screen having a diameter of about 9–10 cm (3½ to 4 in.) and side walls about 2.5 cm (1 in.) high, and wash fiber on the screen with a stream of water using a pressure not exceeding a head (vertical distance between upper level of water and outlet of glass tube) of 152 cm (60 in.), delivered through a glass tube 7.6 cm (3 in.) long and 3 mm (⅛ in.) inside diameter inserted into a rubber tube of 6 mm (¼ in.) inside diameter. Wash the pulpy portion of the material through the screen and continue washing until the remaining fibrous material, moistened with phenolphthalein solution, does not show any red color after standing 5 minutes. Again wash to remove phenolphthalein. Dry the screen containing the fibrous material for 2 hours at 100°C, cool, weigh, and deduct weight of screen. Divide the weight of fibrous material by the weight of combined deseeded pods, trimmings, and strings and multiply by 100 to obtain the percentage of fibrous material.

(ix) If the drained weight recorded in paragraph (b)(2)(i) of this section was less than 340 g (12 oz.), open and examine separately for extraneous material, as directed in paragraph (b)(2)(iv) of this section, additional containers until a total of not less than 340 g (12 oz.) of drained material is obtained. To determine the number of pieces of extraneous vegetable material per 340 g (12 oz.) of drained weight, total the number of pieces of extraneous vegetable material found in all containers opened, divide this sum by the sum of the drained weights in these containers and multiply by 340.

(3) Sampling and acceptance procedure: A lot is to be considered acceptable when the number of "defectives" does not exceed the acceptance number in the sampling plans given in paragraph (b)(3)(ii) of this section, except extraneous plant material, which is based on an average of all the containers examined.

(i) Definitions of terms to be used in the sampling plans in paragraph (b)(3)(ii) of this section are as follows:

(*a*) *Lot.* A collection of primary containers or units of the same size, type, and style manufactured or packed under similar conditions and handled as a single unit of trade.

(*b*) *Lot size.* The number of primary containers or units in the lot.

(*c*) *Sample size* (*n*). The total number of sample units drawn for examination from a lot.

(*d*) *Sample unit.* A container, the entire contents of a container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for the examination or testing as a single unit.

(*e*) *Defective.* Any sample unit shall be regarded as defective when any of the defects or conditions specified in the standard of quality under paragraph (b)(1) of this section are present in excess of the stated tolerances.

(*f*) *Acceptance number* (*c*). The maximum number of defective sample units permitted in the sample in order to consider the lot as meeting the specified requirements.

(*g*) *Acceptable quality level* (*AQL*). The maximum percent of defective sample units permitted in a lot that will be accepted approximately 95 percent of the time.

(ii) Sampling plans and acceptance procedure:

Acceptable Quality Level 6.5

Lot size (primary containers):	Size of container	
	Net weight equal to or less than 1 kg (2.2 lb)	
	n	c
4,800 or less	13	2
4,801 to 24,000	21	3
24,001 to 48,000	29	4
48,001 to 84,000	48	6
84,001 to 144,000	84	9
144,001 to 240,000	126	13
Over 240,000	200	19
	Net weight greater than 1 kg (2.2 lb) but not more than 4.5 kg (10 lb)	
	n	c
2,400 or less	13	2
2,401 to 15,000	21	3
15,001 to 24,000	29	4
24,001 to 42,000	48	6
42,001 to 72,000	84	9
72,001 to 120,000	126	13
Over 120,000	200	19
	Net weight greater than 4.5 kg (10 lb)	
	n	c
600 or less	13	2
601 to 2,000	21	3
2,001 to 7,200	29	4
7,201 to 15,000	48	6
15,001 to 24,000	84	9
24,001 to 42,000	126	13
Over 42,000	200	19

n=number of primary containers in sample.
c=acceptance number.

(4) If the quality of the canned green beans or canned wax beans falls below the standard of quality prescribed by paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in § 130.14 (a) of this chapter, in the manner and form therein specified; but in lieu of the words prescribed for the second line inside the rectangle the following words may be used, when the quality of canned green beans or canned wax beans falls below the standard in one only of the following respects:

(i) "Excessive number very short pieces", if the canned green beans or canned wax beans fail to meet the requirements of paragraph (b)(1)(i) of this section.

(ii) "Excessive number blemished units", if they fail to meet the requirements of paragraph (b)(1)(iv) of this section.

(iii) "Excessive number unstemmed units", if they fail to meet the requirements of paragraph (b)(1)(v) of this section.

(iv) "Excessive foreign material", if they fail to meet the requirements of paragraph (b)(1)(vi) of this section.

§ 155.130 Canned corn.

(a) *Identity*—(1) *Definition.* Canned sweet corn is the product prepared from clean, sound kernels of sweet corn packed with a suitable liquid packing medium which may include water and the creamy component from corn kernels. The tip caps are removed. The product is of the optional styles specified in paragraph (a)(2) of this section. It may contain one, or any combination of two or more, of the optional ingredients set forth in paragraph (a)(3) of this section. Such food is processed by heat, in an appropriate manner, before or after being sealed in a container, so as to prevent spoilage.

(2) *Styles.* The optional styles referred to in paragraph (a)(1) of this section consist of succulent sweet corn of the yellow (golden) or white color type, conforming to *Zea mays* L. having the sweet corn characteristic as follows:

(i) Whole kernel or whole grain or cut kernel consisting of whole or substantially whole cut kernels packed with a liquid medium.

(ii) Cream style consisting of whole or partially whole cut kernels packed in a creamy component from the corn kernels and other liquid or other ingredients to form a product of creamy consistency.

(3) *Optional ingredients.* The following safe and suitable optional ingredients may be used:

(i) Salt.

(ii) Monosodium glutamate.

(iii) Disodium inosinate.

(iv) Disodium guanylate.

(v) Hydrolyzed vegetable protein.

(vi) Autolyzed yeast extract.

(vii) Nutritive carbohydrate sweeteners.

(viii) Spice.

(ix) Flavoring (except artificial).

(x) Citric acid.

(xi) Starch or food starch-modified in cream style corn when necessary to ensure smoothness.

(xii) Seasonings and garnishes.

(*a*) Mint leaves.

(*b*) Pieces of green peppers or red peppers, or mixtures of both, either of which may be sweet or hot and may be dried, or other vegetables, not exceeding 15 percent by weight of the finished food.

(*c*) Lemon juice or concentrated lemon juice.

(*d*) Butter or margarine in a quantity not less than 3 percent by weight of the finished food. When butter or margarine is added, emulsifiers or stabilizers, or both, may be added. When butter or margarine is added, no spice, or flavoring simulating the color or flavor imparted by butter or margarine is used.

(4) *Labeling.* The name of the food is "corn" or "sweet corn" or "sugar corn" and shall include a declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice, seasoning or garnishing that characterizes the product; for example, "With added spice", "Seasoned with red peppers", "Seasoned with butter". The name of the food shall also include the following:

(i) The optional style of the corn ingredient as specified in paragraph (a)(2) of this section.

(ii) The words "vacuum pack" or "vacuum packed" when the corn ingredient is as specified in paragraph (a)(2)(i) of this section and the weight of the liquid in the container, as determined by the method prescribed in paragraph (b)(2)(i) of this section, is not more than 20 percent of the net weight, and the container is closed under conditions creating a high vacuum in the container.

(iii) The color type used only when the product consists of white corn.

(iv) The color type used only when the product consists of white corn.

(5) *Ingredient statement.* Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(b) *Quality*—(1) The standard of quality for canned corn is as follows:

(i) When tested by the method prescribed in paragraph (b)(2) of this section, canned whole-kernel corn (paragraph (a)(2)(i) of this section):

(*a*) Contains not more than seven brown or black discolored kernels or pieces of kernel per 400 g. (14 ounces) of drained weight;

(*b*) Contains not more than 1 cubic centimeter of pieces of cob for each 400 g. (14 ounces) of drained weight;

(*c*) Contains not more than 7 square centimeters (1.1 square inch) of husk per 400 g. (14 ounces) of drained weight; and

(*d*) Contains not more than 180 mm. (7 inches) of silk per 28 g. (1 ounce) of drained weight.

(ii) When tested by the method prescribed in paragraph (b)(3) of this section, canned cream style corn (paragraph (a)(2)(ii) of this section):

(*a*) Contains not more than 10 brown or black discolored kernels or pieces of kernel per 600 g. (21.4 ounces) of net weight;

(*b*) Contains not more than 1 cubic centimeter of pieces of cob per 600 g. (21.4 ounces) of net weight;

(*c*) Contains not more than 7 square centimeters (1.1 square inch) of husk per 600 g. (21.4 ounces) of net weight;

(*d*) Contains not more than 150 mm. (6 inches) of silk for each 28 g. (1 ounce) of net weight; and

(*e*) Has a consistency such that the average diameter of the approximately circular area over which the prescribed sample spreads does not exceed 30.5 cm. (12 inches), except that when the washed drained material contains more than 20 percent of alcohol-insoluble solids, the average diameter of the approximately circular area over which the prescribed sample spreads does not exceed 25.4 cm. (10 inches).

(iii) (*a*) The weight of the alcohol-insoluble solids of whole-kernel corn (paragraph (a)(2)(i) of this section) does not exceed 27 percent of the drained weight, when tested by the method prescribed in paragraph (b)(2) of this section.

(*b*) The weight of the alcohol-insoluble solids of the washed drained material of cream style corn (paragraph (a)(2)(ii) of this section) does not exceed 27 percent of the drained weight of such material, when tested by the method prescribed in paragraph (b)(3) of this section.

(2) The method referred to in paragraph (b)(1) of this section for testing whole-kernel corn (paragraph (a)(2)(i) of this section) is as follows:

(i) Determine the gross weight of the container. Open and distribute the con-

tents of the container over the meshes of a U.S. No. 8 circular sieve which has previously been weighed. The diameter of the sieve is 20.3 cm. (8 inches) if the quantity of the contents of the container is less than 1.36 kg. (3 pounds), and 30.5 cm. (12 inches) if such quantity is 1.36 kg. (3 pounds) or more. The bottom of the sieve is woven-wire cloth which complies with the specifications for such sieve set forth in the "Definitions of Terms and Explanatory Notes," page xviii, of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th edition, 1970.[2] Without shifting the material on the sieve, so incline the sieve at approximately 17–20° angle to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and the drained material. Record, in g. (ounces), the weight so found, less the weight of the sieve, as the drained weight. Dry and weigh the empty container and subtract this weight from the gross weight to obtain the net weight. Calculate the percent of drained liquid in the net weight.

(ii) Pour the drained material from the sieve into a flat tray and spread it in a layer of fairly uniform thickness. Count, but do not remove, the brown or black discolored kernels or pieces of kernel and calculate the number per 400 g. (14 ounces) of drained material. Remove pieces of silk more than 12.7 mm. (one-half inch) long, husk, cob, and any pieces of material other than corn. Measure the aggregate length of such pieces of silk and calculate the length of silk per 28 g. (1 ounce) of drained weight. Spread the husk flat, measure its aggregate area, and calculate the area of husk per 400 g. (14 ounces) of drained weight. Place all pieces of cob under a measured amount of water in a cylinder which is so graduated that the volume can be measured to 0.1 cubic centimeter. Take the increase in volume as the aggregate volume of the cob and calculate the volume of cob per 400 g. (14 ounces) of drained weight.

(iii) Comminute a representative 100 g. sample of the drained corn from which the silk, husk, cob, and other material which is not corn (i.e., peppers) have been removed. An equal amount of water is used to facilitate this operation. Weigh to nearest 0.01 g. a portion of the comminuted material equivalent to approximately 10 g. of the drained corn into a 600 cubic centimeter beaker. Add 300 cubic centimeters of 80 percent alcohol (by volume), stir, cover beaker, and bring to a boil. Simmer slowly for 30 minutes. Fit a Buchner funnel with a previously prepared filter paper of such sizes that its edges extend 12.7 mm. (one-half inch) or more up the vertical sides of the funnel. The previous preparation of the filter paper consists of drying it in a flat-bottomed dish for 2 hours at 100° C, covering the dish with a tight fitting cover, cooling it in a desiccator, and promptly weighing to the nearest 0.001 g. After the filter paper is fitted to the funnel, apply suction and transfer the contents of the beaker to the funnel. Do not allow any of the material to run over the edge of the paper. Wash the material on the filter with 80 percent alcohol (by volume) until the washings are clear and colorless. Transfer the filter paper with the material retained thereon to the dish used in preparing the filter paper. Dry the material in a ventilated oven, without covering the dish, for 2 hours at 100° C. Place the cover on the dish, cool it in a desiccator, and promptly weigh to the nearest 0.001 g. From this weight subtract the weight of the dish, cover, and paper as previously found. Calculate the remainder to percentage.

(3) The method referred to in paragraph (b)(1) of this section for testing cream-style corn (paragraph (a)(2)(ii) of this section) is as follows:

(i) Allow the container to stand at least 24 hours at a temperature of 68° F to 85° F. Determine the gross weight, open, transfer the contents into a pan, and mix thoroughly in such a manner as not to incorporate air bubbles. (If the net contents of a single container is less than 510 g. (18 ounces) determine the gross weight, open, and mix the contents of the least number of containers necessary to obtain 510 g. (18 ounces). Fill level full a hollow, truncated cone so placed on a polished horizontal plate as to prevent leakage. The cone has an inside bottom diameter of 7.62 cm. (3 inches), inside top diameter of 5.08 cm. (2 inches), and height of 12.30 cm. (4 27/32 inches). As soon as the cone is filled, lift it vertically. Determine the average of the longest and shortest diameters of the approximately circular area on the plate covered by the sample 30 seconds after lifting the cone. Dry and weigh each empty container and subtract the weight so found from the gross weight to obtain the net weight.

(ii) Transfer the material from the plate, cone, and pan onto a U.S. No. 8 sieve as prescribed in paragraph (b)(2)(i) of this section. The diameter of the sieve is 20.3 cm. (8 inches) if the quantity of the contents of the container is less than 1.36 kg. (3 pounds), and 30.5 cm. (12 inches) if such quantity is 1.36 kg. (3 pounds) or more. Set the sieve in a pan. Add enough water to bring the level within 9.53 mm. (three-eighth inch) to 6.35 mm. (one-fourth inch) of the top of the sieve. Gently wash the material on the sieve by combined up-and-down and circular motion for 30 seconds. Repeat washing with a second portion of water. Remove sieve from pan, incline to facilitate drainage, and drain for 2 minutes.

(iii) From the material remaining on the U.S. No. 8 sieve, count, but do not remove, the brown or black discolored kernels or pieces of kernel and calculate the number per 600 g. (21.4 ounces) of net weight. Remove pieces of silk more than 12.7 mm. (one-half inch) long, husk, cob, and other material which is not corn (i.e., peppers). Measure aggregate length of such pieces of silk and calculate the length per 28 g. (ounce) of net weight. Spread the husk flat and measure its aggregate area and calculate the area per 600 g. (21.4 ounces) of net weight. Place all pieces of cob under a measured amount of water in a cylinder which is so graduated that the volume may be measured to 0.1 cubic centimeter. Take the increase in volume as the aggregate volume of the cob and calculate the volume of cob per 600 g. (21.4 ounces) of net weight. Take a representative 100 g. sample of the material remaining on the U.S. No. 8 sieve (if such material weighs less than 100 g. take all of it) and determine the alcohol-insoluble solids as prescribed in paragraph (b)(2)(iii) of this section for whole kernel corn.

(4) Sampling and acceptance procedure. A lot is to be considered acceptable when the number of "defectives" does not exceed the acceptance number in the sampling plans given in paragraph (b)(4)(ii) of this section.

(i) Definitions of terms to be used in the sampling plans in paragraph (b)(4)(ii) of this section are as follows:

(*a*) *Lot.* A collection of primary containers or units of the same size, type, and style manufactured or packed under similar conditions and handled as a single unit of trade.

(*b*) *Lot size.* The number of primary containers or units in the lot.

(*c*) *Sample size* (*n*). The total number of sample units drawn for examination from a lot.

(*d*) *Sample unit.* A container, the entire contents of a container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for the examination or testing as a single unit.

(*e*) *Defective.* Any sample unit shall be regarded as defective when any of the defects or conditions specified in the quality (paragraph (b)(1) of this section) and fill of container (paragraph (c) of this section) standards are present in excess of the stated tolerances.

(*f*) *Acceptance number* (*c*). The maximum number of defective sample units permitted in the sample in order to consider the lot as meeting the specified requirements.

(*g*) *Acceptable quality level* (*AQL*). The maximum percent of defective sample units permitted in a lot that will be accepted approximately 95 percent of the time.

[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

(ii) Sampling plans and acceptance procedure:

Acceptable quality level 6.5

Lot size (primary containers)	Size of container	
	Net weight equal to or less than 1 kg (2.2 lb)	
	n	*c*
4,800 or less	13	2
4,801 to 24,000	21	3
24,001 to 48,000	29	4
48,001 to 84,000	48	6
84,001 to 144,000	84	9
144,001 to 240,000	126	13
Over 240,000	200	19
	Net weight greater than 1 kg (2.2 lb) but not more than 4.5 kg (10 lb).	
	n	*c*
2,400 or less	13	2
2,401 to 15,000	21	3
15,001 to 24,000	29	4
24,001 to 42,000	48	6
42,001 to 72,000	84	9
72,001 to 120,000	126	13
Over 120,000	200	19
	Net weight greater than 4.5 kg (10 lb)	
	n	*c*
600 or less	13	2
601 to 2,000	21	3
2,001 to 7,200	29	4
7,201 to 15,000	48	6
15,001 to 24,000	84	9
24,001 to 42,000	126	13
Over 42,000	200	19

n=number of primary containers in sample.
c=acceptance number.

(5) If the quality of canned corn falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in § 130.14(a) of this chapter, in the manner and form therein specified; however, if the quality of the canned corn falls below standard with respect to only one of the factors of quality specified by paragraph (b)(1)(i) (*a*) to (*d*) of this section, or by paragraph (b)(1)(ii) (*a*) to (*e*) of this section, there may be substituted for the second line of such general statement of substandard quality, "Good food—not high grade", a new line as specified after the corresponding subdivision designation of paragraph (b)(1) of this section, which the canned corn fails to meet:

(i) (*a*) or (ii) (*a*) "Excessive discolored kernels".
(i) (*b*) or (ii) (*b*) "Excessive cob".
(i) (*c*) or (ii) (*c*) "Excessive husk".
(i) (*d*) or (ii) (*d*) "Excessive silk".
(ii) (*e*) "Excessively liquid".

(c) *Fill of container*—(1) The standard of fill of container for canned corn is:

(i) Except in the case of vacuum pack corn the fill of the corn ingredient and packing medium, as determined by the general method for fill of container prescribed in §130.12(b) of this chapter, is not less than 90 percent of the total capacity of the container.

(ii) In whole kernel corn, the drained weight of the corn ingredient, as determined by sections 32.001 and 32.002 *Canned Products—Drained Weight—Procedure*, in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th edition, 1970, page 559, shall not be less than 61 percent of the water capacity of the container.

(2)(i) A container that falls below the requirement for minimum fill prescribed in paragraph (c)(1)(i) of this section is considered a "defective." The food will be deemed to fall below the standard of fill when the number of defectives exceeds the acceptance number (c) in the sampling plans prescribed in paragraph (b)(4) of this section.

(ii) Whole kernel will be deemed to fall below the standard of fill when the average drained weight of all of the containers examined according to the sampling plans prescribed in paragraph (b)(4) of this section is less than that prescribed in paragraph (c)(1)(ii) of this section.

(3) If canned corn falls below the standard of fill of container prescribed in paragraphs (c)(1) and (2) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

§ 155.131 Canned field corn.

(a) *Identity*—(1) Canned field corn conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for canned corn by § 155.130(a), except that the corn ingredient consists of succulent field corn or a mixture of succulent field corn and succulent sweet corn.

(2) The name of the food conforms to the name specified in § 155.130(a)(5), except that the words "Corn", "Sweet corn", and "Sugar corn" are replaced by the words "Field corn", and the term "Golden field corn" is not used.

(b) [Reserved.]

(c) *Fill of container.* Canned cream-style field corn conforms to the standard of fill of container and label statement of substandard fill prescribed for canned cream-style corn by § 155.130(c).

§ 155.170 Canned peas.

(a) *Identity*—(1) Canned peas is the food prepared from one of the optional pea ingredients, specified in paragraph (a)(1), of this section, and water. The food may contain one or more of the optional ingredients specified in paragraph (a)(2) of this section and one or more of the optional seasonings specified in paragraph (a)(3) of this section. The food is sealed in a container and so processed by heat as to prevent spoilage. The optional pea ingredients are:

(i) Shelled, succulent peas (*Pisum sativum*) of Alaska or other smooth skin varieties.

(ii) Shelled, succulent peas (*Pisum sativum*) of sweet, wrinkled varieties.

(2) The following optional ingredients may be used:

(i) Salt.

(ii) Monosodium glutamate.

(iii) Disodium inosinate complying with the provisions of § 172.535 of this chapter.

(iv) Disodium guanylate complying with the provisions of § 172.530 of this chapter.

(v) Hydrolyzed vegetable protein.

(vi) Autolyzed yeast extract.

(vii) Sugar.

(viii) Dextrose.

(ix) Spice.

(x) Flavoring (except artificial).

(xi) Artificial coloring.

(xii) Sodium carbonate, sodium bicarbonate, sodium hydroxide, calcium hydroxide, magnesium hydroxide, magnesium oxide, magnesium carbonate, or any mixture or combination of these in such quantity that the pH of the finished canned peas is not more than 8, as determined by the glass electrode method for the hydrogen ion concentration.

(3) The food may be seasoned with one or more of the following optional seasonings:

(i) Green peppers or red peppers, which may be dried.

(ii) Mint leaves.

(iii) Onions, which may be dried.

(iv) Garlic, which may be dried.

(v) Horseradish.

(vi) Lemon juice or concentrated lemon juice.

(vii) Butter or margarine in a quantity not less than 3 percent by weight of the finished food. When butter or margarine is added, safe and suitable emulsifiers or stabilizers, or both, may be added. When butter or margarine is added, no spice, flavoring, or coloring simulating the flavor or color imparted by butter or margarine is used.

(4) The name of the optional pea ingredient is "early" or "June" or "early June", "sweet" or "sweet wrinkled" or "sugar".

(5) If artificial coloring is present, the label shall state that fact in such manner and form as provided in paragraph (b)(3) of this section.

(6) The name of the food is "peas". The name of the food shall include a declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter, and a declaration of any spice or seasoning that characterizes the product; for example, "with added spice", "seasoned with red peppers", "seasoned with butter". Whenever the name "peas" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the name of the optional pea ingredient present as specified in paragraph (a)(4) of this section, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter, except that the specified varietal name of the peas may so intervene.

(7) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(b) *Quality*—(1) The standard of quality for canned peas is as follows:

(i) Not more than 4 percent by count of the peas in the container are spotted or otherwise discolored;

(ii) Standard canned peas are normally colored, not artificially colored;

(iii) The combined weight of pea pods and other harmless extraneous vegetable

material is not more than one-half of 1 percent of the drained weight of peas in the container;

(iv) The weight of pieces of peas is not more than 10 percent of the drained weight of peas in the container;

(v) The skins of not more than 25 percent by count of the peas in the container are ruptured to a width of 1/16 inch or more;

(vi) Not less than 90 percent by count of the peas in the container are crushed by a weight of not more than 907.2 grams (2 pounds); and

(vii) The alcohol-insoluble solids of Alaska or other smooth skin varieties of peas in the container are not more than 23.5 percent, and of sweet, wrinkled varieties, not more than 21 percent.

(2) Canned peas shall be tested by the following methods to determine whether or not they meet the requirements of paragraph (b)(1) of this section:

(i) After determining the fill of the container as prescribed in paragraph (c)(1) of this section, distribute the contents of the container over the meshes of a circular sieve made with No. 8 woven-wire cloth which complies with the specifications for such cloth set forth on page 3 of "Standard Specifications for Sieves," published October 25, 1938, by United States Department of Commerce, National Bureau of Standards. The diameter of the sieve used is 8 inches if the quantity of the contents of the container is less than 3 pounds, or 12 inches if such quantity is 3 pounds or more. Without shifting the peas, so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, remove the peas from the sieve and weigh them. Such weight shall be considered to be the drained weight of the peas.

(ii) From the drained peas obtained in paragraph (b)(2)(i) of this section, promptly segregate and weigh the pea pods and other harmless extraneous vegetable material, and the pieces of peas.

(iii) From the drained peas obtained in paragraph (b)(2)(i) of this section, take at random a subdivision of 100 to 150 peas, and count them. Immediately cover these peas with a portion of the liquid obtained in paragraph (b)(2)(i) of this section, and add the remaining liquid to the drained peas from which the subdivision was taken. Count those peas in the subdivision which are spotted or otherwise discolored, and also those peas the skins of which are ruptured to a width of 1/16 inch or more.

(iv) Immediately after each pea is examined by the method prescribed in paragraph (b)(2)(iii) of this section, test it by removing its skin, placing one of its cotyledons, with flat surface down, on the approximate center of the level, smooth surface of a rigid plate, lowering a horizontal disc to the highest point of the cotyledon, and measuring the height of the cotyledon. The disc is of rigid material and is affixed to a rod held vertically by a support through which the rod can freely move upward or downward. The lower face of the disc is a smooth, plane surface horizontal to the vertical axis of the rod. A device to which weight may be added is affixed to the upper end of the rod. Before lowering the disc to the cotyledon, adjust the combined weight of disc, rod, and device to 100 grams. After measuring the height of the cotyledon, and shifting the plate, if necessary, so that the cotyledon is under the approximate center of the disc, add weight to the device at a uniform, continuous rate of 12 grams per second until the cotyledon is pressed to one-fourth its previously measured height, or until the combined weight of disc, rod, and device is 907.2 grams (2 pounds). A pea so tested shall be considered to be crushed when its cotyledon is pressed to one-fourth its original height.

(v) Drain the liquid from the peas which remained after taking the subdivision as prescribed in paragraph (b)(2)(iii) of this section. Transfer the peas to a pan, and rinse them with a volume of water equal to twice the capacity of the container from which such peas were drained in paragraph (b)(2)(i) of this section. Immediately drain the peas again by the method prescribed in paragraph (b)(2)(i) of this section. After the 2 minutes' draining, wipe the moisture from the bottom of the sieve. Comminute the peas thus drained, stir them to a uniform mixture, and weigh 20 grams of such mixture into a 600 cc beaker. Add 300 cc. of 80 percent alcohol (by volume), stir, cover beaker, and bring to a boil. Simmer slowly for 30 minutes. Fit a Buchner funnel with a previously prepared filter paper of such size that its edges extend 1/2 inch or more up the vertical sides of the funnel. The previous preparation of the filter paper consists of drying it in a flat-bottomed dish for 2 hours at 100° C, covering the dish with a tight-fitting cover, cooling it in a desiccator, and promptly weighing. After the filter paper is fitted to the funnel, apply suction and transfer the contents of the beaker to the funnel. Do not allow any of the material to run over the edge of the paper. Wash the material on the filter with 80 percent alcohol (by volume) until the washings are clear and colorless. Transfer the filter paper with the material retained thereon to the dish used in preparing the filter paper. Dry the material in a ventilated oven, without covering the dish, for 2 hours at 100° C. Place the cover on the dish, cool it in a desiccator, and promptly weigh. From this weight, subtract the weight of the dish, cover, and paper, as previously found. The weight in grams thus obtained, multiplied by 5, shall be considered to be the percent of alcohol-insoluble solids.

(3) If the quality of canned peas falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in § 130.14(a) of this chapter, in the manner and form therein specified; but in lieu of such general statement of substandard quality when the quality of canned peas falls below the standard in only one respect, the label may bear the alternative statement "Below standard in quality _____", the blank to be filled in with the words specified after the corresponding subparagraph number of paragraphs (b)(1) of this section which such canned peas fail to meet, as follows: (i) "Excessive discolored peas"; (ii) "Artificially colored"; (iii) "Excessive foreign material"; (iv) "Excessive broken peas"; (v) "Excessive cracked peas"; (vi) "Not tender"; (vii) "Excessively mealy". Such alternative statement shall immediately and conspicuously precede or follow without intervening written, printed, or graphic matter, the name "Peas" and any words and statements required or authorized to appear with such name by paragraph (a)(4) of this section.

(c) *Fill of container*—(1) The standard of fill of container for canned peas is a fill such that, when the peas and liquid are removed from the container and returned thereto, the leveled peas (irrespective of the quantity of the liquid), 15 seconds after they are so returned completely fill the container. A container with lid attached by double seam shall be considered to be completely filled when it is filled to the level 3/16 inch vertical distance below the top of the double seam; and a glass container shall be considered to be completely filled when it is filled to the level 1/2 inch vertical distance below the top of the container.

(2) If canned peas fall below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

§ 155.172 Canned dry peas.

Canned dry peas conforms to the definition and standard of identity, and is subject to requirements for label statement of optional ingredients prescribed for canned peas by § 155.170(a), except that:

(a) *Identity*—(1) The optional pea ingredients are:

(i) Shelled, dry peas (*Pisum sativum*) of Alaska or other smooth skin varieties.

(ii) Shelled, dry peas (*Pisum sativum*) of sweet, wrinkled varieties.

(2) The optional ingredients specified in § 155.170(a)(2)(xii) shall not be used.

(3) The name of the food is "Cooked dry peas" or "Soaked dry peas". The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The optional pea ingredient names specified by § 155.170(a)(4) shall not be used on labels.

(b) *Quality*—(1) The standard of quality for canned dry peas is that specified for canned peas by § 155.170(b)(1) and (2), except that:

(i) The alcohol insoluble solids maximums specified in § 155.170(b)(1)(vii) do not apply.

(ii) The alcohol insoluble solids methods specified in § 155.170(b)(2)(v) is not used.

(2) If the quality of canned dry peas falls below the standard of quality prescribed by paragraph (b)(1) of this section the label shall bear the statement of

substandard quality in the manner and form specified in § 155.170(b)(3) for canned peas, except that words "Excessively mealy" shall not be used.

(c) *Fill of container*—(1) The standard of fill of container for canned dry peas is that prescribed for canned peas by § 155.170(c)(1).

(2) If canned dry peas fall below the standard of fill of container prescribed by paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

§ 155.190 Canned tomatoes.

(a) *Identity*—(1) *Description*—(i) Canned tomatoes is the food prepared from mature tomatoes conforming to the characteristics of the fruit *Lycopersicum esculentum* P. Mill, of red or reddish varieties. The tomatoes may or may not be peeled, but shall have had the stems and calicies removed and shall have been cored, except where the internal core is insignificant to texture and appearance.

(ii) Canned tomatoes may contain one or more of the safe and suitable optional ingredients specified in paragraph (a)(2) of this section, be packed without any added liquid or in one of the optional packing media specified in paragraph (a)(3) of this section and be prepared in one of the styles specified in paragraph (a)(4) of this section. Such food is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

(2) *Optional ingredients.* One or more of the following safe and suitable ingredients may be used:

(i) Calcium salts in a quantity reasonably necessary to firm the tomatoes, but the amount of calcium in the finished canned tomatoes is not more than 0.045 percent of the weight, except that when the tomatoes are prepared in one of the styles specified in paragraph (a)(4) (iv) to (vi) of this section the amount of calcium is not more than 0.08 percent of the weight of the food.

(ii) Organic acids for the purpose of acidification.

(iii) Dry nutritive carbohydrate sweeteners whenever any organic acid provided for in paragraph (a)(2)(ii) of this section is used, in a quantity reasonably necessary to compensate for the tartness resulting from such added acid.

(iv) Salt.

(v) Spices, spice oils.

(vi) Flavoring and seasoning.

(vii) Natural vegtable ingredients such as onion, peppers, and celery in a quantity not more than 10 percent by weight of the finished food.

(3) *Packing media.* (i) The liquid draining from the tomatoes during or after peeling or coring.

(ii) The liquid strained from the residue from preparing tomatoes for canning consisting of peels and cores with or without tomatoes or pieces thereof.

(iii) The liquid strained from mature tomatoes.

(iv) Tomato juice, tomato puree or tomato pulp or tomato paste complying with the compositional requirements of §§ 155.191, 155.192, and 156.145 of this chapter.

(4) *Styles.* (i) Whole.

(ii) Whole and pieces.

(iii) Pieces.

(iv) Diced.

(v) Sliced.

(vi) Wedges.

(5) *Name of the food.* (i) The name of the food is "tomatoes", except that when the tomatoes are not peeled the name is "unpeeled tomatoes".

(ii) The following shall be included as part of the name or in close proximity to the name of the food:

(*a*) A declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter.

(*b*) A declaration of any added spice, seasoning, or natural vegetable ingredient that characterizes the product, (e.g., "with added_____" or, "with_____" the blank to be filled in with the word(s) "spice(s)", "seasoning(s)", or the name (s) of the vegetable(s) used or in lieu of the word(s) "spice(s)" or "seasoning (s)", the common or usual name(s) of the spice(s) or seasoning(s) used) except that no declaration of the presence of onion, peppers, and celery is required for stewed tomatoes.

(*c*) The word "stewed" if the tomatoes contain characterizing amounts of at least the three optional vegetables listed in paragraph (a)(2)(vii) of this section.

(*d*) The styles: "whole and pieces", "pieces", "diced", "sliced", or "wedges", as appropriate.

(*e*) The name of the packing medium: "tomato paste", "tomato puree", or "tomato pulp" as provided in paragraph (a)(3)(iv) of this section, or "strained residual tomato material from preparation for canning" as provided for in paragraph (a)(3)(ii) of this section, as appropriate. The name of the packing medium shall be preceded by the word "with".

(iii) The following may be included as part of the name or in close proximity to the name:

(*a*) The word "whole" if the tomato ingredient present is whole or almost whole and the drained weight as determined in accordance with the method prescribed in paragraph (b)(2) of this section is not less than 80 percent of the finished food.

(*b*) The words "solid pack" when none of the optional packing media specified in paragraph (a)(3) of this section are used.

(*c*) The words "in tomato juice" if the packing medium specified in paragraph (a)(3)(iv) of this section is used.

(6) *Label declaration of optional ingredients.* The name of each optional ingredent used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(b) *Quality*—(1) The standard of quality for canned tomatoes is as follows:

(i) The drained weight, as determined by the method prescribed in paragraph (b)(2)(i) of this section, is not less than 50 percent of the weight of water required to fill the container, as determined by the general method for water capacity of containers prescribed in § 130.12(a) of this chapter;

(ii) The strength and redness of color as determined by the method prescribed in paragraph (b)(2) of this section, are not less than that of the blended color of any combination of the color discs described in such method in which one-third the area of disc 1, and not more than one-third the area of disc 2, is exposed;

(iii) Peel per kilogram (2.2 pounds) of the finished food covers an area of not more than 15 cm^2 (2.3 square inches) (6.8 cm^2 (1.06 square inch) per pound) on average of all containers examined provided, however, the area of peel is not a factor of quality for canned unpeeled tomatoes labeled in accordance with paragraph (a)(5)(i) of this section; and

(iv) Blemishes per kilogram (2.2 pounds) of the finished food cover an area of not more than 3.5 cm^2 (0.54 square inch) (1.6 cm^2 (0.25 square inch) per pound) based on an average of all containers examined.

(2) Canned tomatoes shall be tested by the following method to determine whether or not they meet the requirements of paragraph (b)(1)(i) and (ii) of this section:

(i) Remove lid from container, but in the case of a container with lid attached by double seam, do not remove or alter the height of the double seam. Tilt the opened container so as to distribute the contents over the meshes of a circular sieve which has previously been weighed. The diameter of the sieve used is 20.3 centimeters (8 inches) if the quantity of the contents of the container is less than 1.4 kilograms (3 pounds) or 30.5 centimeters (12 inches) if such quantity is 1.4 kilograms (3 pounds) or more. The meshes of such sieve are made by so weaving wire of 1.4 mm (0.054 inch) diameter as to form square openings 11.3 mm by 11.3 mm (0.446 inch by 0.446 inch). Without shifting the tomatoes, so incline the sieve as to facilitate drainage of the liquid. Two minutes from the time drainage begins, weigh the sieve and drained tomatoes. The weight so found, less the weight of the sieve, shall be considered to be the drained weight.

(ii) Remove from the sieve the drained tomatoes, cut out and segregate successively those portions of least redness until 50 percent of the drained weight has been so segregated. Comminute the segregated portions to a uniform mixture without removing or breaking the seeds. Fill the mixture into a black container to a depth of at least 25.4 mm (1 inch). Free the mixture from air bubbles, and skim off or press below the surface all visible seeds. Compare the color of the mixture, in full diffused daylight or its equivalent, with the blended color of combinations of the following concentric Munsell color discs of equal diameter, or the color equivalent of such discs:

(*a*) Red—Munsell 5 R 2.6/13 (glossy finish).

(b) Yellow—Munsell 2.5 YR 5/12 (glossy finish).

(c) Black—Munsell N 1/ (glossy finish).

(d) Grey—Munsell N 4 (mat finish).

(3) *Sampling and acceptance procedure.* A lot is to be considered acceptable when the number of "defectives" does not exceed the acceptance number in the sampling plans given in paragraph (b) (3) (ii) of this section.

(i) Definitions of terms to be used in the sampling plans in paragraph (b) (3) (ii) of this section are as follows:

(a) *Lot.* A collection of primary containers or units of the same size, type, and style manufactured or packed under similar conditions and handled as a single unit of trade.

(b) *Lot size.* The number of primary containers or units in the lot.

(c) *Sample size (n).* The total number of sample units drawn for examination from a lot.

(d) *Sample unit.* A container, the entire contents of a container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for examination or testing as a single unit.

(e) *Defective.* Any sample unit shall be regarded as defective when the sample unit does not meet the criteria set forth in the standards.

(f) *Acceptance number (c).* The maximum number of defective sample units permitted in the sample in order to consider the lot as meeting the specified requirements.

(g) *Acceptable quality level (AQL).* The maximum percent of defective sample units permitted in a lot that will be accepted approximately 95 percent of the time.

(ii) Sampling plans and acceptance procedure:

Acceptable Quality level 6.5

Lot size (primary containers)	Size of container	
	Net weight equal to or less than 1 kg (2.2 lb.)	
	n	c
4,800 or less	13	1
4,801 to 24,000	21	3
24,001 to 48,000	29	4
48,001 to 84,000	48	5
84,001 to 144,000	84	9
144,001 to 240,000	126	13
Over 240,000	200	19
	Net weight greater than 1 kg (2.2 lb.) but not more than 4.5 kg (10 lb.)	
	n	c
2,400 or less	13	2
2,401 to 15,000	21	3
15,001 to 24,000	29	4
24,001 to 42,000	48	6
42,001 to 72,000	84	9
72,001 to 120,000	126	13
Over 120,000	200	19
	Net weight greater than 4.5 kg (10 lb.)	
	n	c
600 or less	13	2
601 to 2,000	21	3
2,001 to 7,200	29	4
7,201 to 15,000	48	6
15,001 to 24,000	84	9
24,001 to 42,000	126	13
Over 42,000	200	19

n=number of primary containers in sample.
c=acceptance number.

(4) If the quality of canned tomatoes falls below the standard prescribed in paragraph (b) (1) of this section, the label shall bear the general statement of substandard quality specified in § 130.14 (a) of this chapter in the manner and form therein specified; if, however, the quality of canned tomatoes falls below standard with respect to only one of the factors of quality specified by paragraph (b) (1) (i) to (iii) of this section, there may be substituted for the second line of such general statement of substandard quality ("Good Food—Not High Grade") a new line, appropriate for the corresponding subparagraph designation of paragraph (b) (1) of this section which the canned tomatoes fail to meet, to read as follows: (i) "Poor color" or (ii) "Excessive peel" or (iii) "Excessive blemishes".

(c) *Fill of container*—(1) The standard of fill of container for canned tomatoes is a fill of not less than 90 percent of the total capacity of the container, as determined by the general method for fill of containers prescribed in § 130.12 (b) of this chapter.

(2) If canned tomatoes fall below the standard of fill of container prescribed in paragraph (c) (1) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

§ 155.191 Tomato paste.

(a) Tomato paste is the food prepared from one or any combination of two or all of the following optional ingredients:

(1) The liquid obtained from mature tomatoes of red or reddish varieties.

(2) The liquid obtained from the residue from preparing such tomatoes for canning, consisting of peelings and cores with or without such tomatoes or pieces thereof.

(3) The liquid obtained from the residue from partial extraction of juice from such tomatoes.

Such liquid is obtained by so straining such tomatoes or residue, with or without heating, as to exclude skins, seeds, and other coarse or hard substances. Prior to straining, food-grade hydrochloric acid may be added to the tomato material at a rate to obtain a pH no lower than 2.0±0.2. Such acid is then neutralized with food-grade sodium hydroxide so that the treated tomato material is restored to a pH of 4.2±0.2, prior to straining. It is concentrated and may be seasoned with one or more of the optional ingredients:

(4) Salt (sodium chloride formed during acid neutralization shall be considered added salt).

(5) Spice.

(6) Flavoring.

It may contain, in such quantity as neutralizes a part of the tomato acids, the optional ingredient:

(7) Baking soda.

When sealed in a container it is so processed by heat, before or after sealing, as to prevent spoilage. It contains not less than 24.0 percent of natural tomato soluble solids as determined by the following method: [1] Determine the refractive index of the clear serum obtained from the product, corrected for temperature, converting the resultant index to "% Sucrose" in accordance with the "International Scale of Refractive Indices of Sucrose at 20° C.," pages 828–30, Reference Tables 43.008 and 43.009 of the book "Official Methods of Analysis of the Association of Official Agricultural Chemists," 10th edition, 1965. If no salt has been added, this percent sucrose from the reference table shall be considered the percent of natural tomato soluble solids. If salt has been added, determine the percent of sodium chloride by the method prescribed on page 519, section 30.009, under "Sodium Chloride–Official," of said book. Subtract the percent of sodium chloride found from the percent of total soluble solids found and multiply the difference by 1.016. The product shall be considered the percent of natural tomato soluble solids.

(b) When the optional ingredient specified in paragraph (a) (2) of this section is present, in whole or in part, the label shall bear the statement "Made from" (or Made in part from", as the case may be) "residual tomato material from canning". When the optional ingredient specified in paragraph (a) (3) of this section is present, in whole or in part, the label shall bear the statement "Made from" (or "Made in part from", as the case may be) "residual tomato material from partial extraction of juice". If both such ingredients are present, such statements may be combined in the statement "Made from" (or "Made in part from", as the case may be) "residual tomato material from canning and from partial extraction of juice". When the optional ingredient specified in paragraph (a) (4), (5), or (6) of this section is present, the label shall bear the statement or statements "Salt added" or "With added salt", "Spice added" or "With added spice", "Flavoring added" or "With added flavoring", as the case may be. When the optional ingredient specified in paragraph (a) (7) of this section is present, the label shall bear the statement "Baking soda added". If two or all of the optional ingredients specified in paragraphs (a) (4), (5), (6), and (7) of this section are present, such statements may be combined; for example, "Salt, spice, flavoring, and baking soda added". In lieu of the word "salt", "spice", or "flavoring" in such statement or statements, the common or usual name of such salt, spice, or flavoring may be used.

(c) Wherever the name "Tomato paste" appears on the label so conspicuously as to be easily seen under custom-

[1] "Collaborative Study of the Determination of Soluble Solids in Tomato Products by Refractive Index Expressed as Percent Sucrose" by Frank C. Lamb, National Canners Association, 1950 Sixth Street, Berkeley, CA 94710, "Journal of the Association of Official Analytical Chemists," vol. 52, No. 5 (1969), pp. 1050–54. Adopted as official, first action at the 1969 AOAC meeting.

ary conditions of purchase, the statement or statements specified in this section, showing the optional ingredients present shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 155.192 Tomato puree.

(a) Tomato puree, tomato pulp, is the food prepared from one or any combination of two or all of the following optional ingredients:

(1) The liquid obtained from mature tomatoes of red or reddish varieties.

(2) The liquid obtained from the residue from preparing such tomatoes for canning, consisting of peelings and cores with or without such tomatoes or pieces thereof.

(3) The liquid obtained from the residue from partial extraction of juice from such tomatoes.

(4) Salt.

Such liquid is obtained by so straining such tomatoes or residue, with or without heating, as to exclude skins, seeds, and other coarse or hard substances. Prior to straining, food-grade hydrochloric acid may be added to the tomato material at a rate to obtain a pH no lower than 2.0±0.2. Such acid is then neutralized with food-grade sodium hydroxide so that the treated tomoto material is restored to a pH of 4.2±0.2, prior to straining. It is concentrated and may be seasoned with salt (sodium chloride formed during acid neutralization shall be considered added salt). When sealed in a container, it is so processed by heat, before or after sealing, as to prevent spoilage. It contains not less than 8.0 percent, but less than 24.0 percent, of natural tomato soluble solids, as determined by the following method: [7] Determine the refractive index of the clear serum obtained from the product, corrected for temperature, converting the resultant index to "% Sucrose" in accordance with the "International Scale of Refractive Indices of Sucrose at 20° C.," pages 931–33, 935, Reference Tables 47.012, 47.013, and 47.015 of the book "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th edition, 1971. If no salt has been added, this percent sucrose from the reference table shall be considered the percent of natural tomato soluble solids. If salt has been added, determine the percent of sodium chloride by the method prescribed on page 561, section 32.017, under "Sodium Chloride—Official," of said book. Subtract the percent of sodium chloride from the percent of total soluble solids found and multiply the difference by 1.016. The product shall be considered the percent of natural tomato soluble solids.

(b) (1) When the optional ingredient specified in paragraph (a) (2) of this section is present, in whole or in part, the label shall bear the statement "Made from residual tomato material from canning" or "Made in part from residual tomato material from canning", as the case may be. When the optional ingredient specified in paragraph (a) (3) of this section is present, in whole or in part, the label shall bear the statement "Made from residual tomato material from partial extraction of juice" or "Made in part from residual tomato material from partial extraction of juice", as the case may be. If both such ingredients are present, such statements may be combined in the statement "Made from residual tomato material from canning and from partial extraction of juice" or "Made in part from residual tomato material from canning and from partial extraction of juice", as the case may be. When the optional ingredient specified in paragraph (a) (4) of this section is present, the label shall bear the statement "Salt added" or "With added salt".

(2) The name specified for the food covered by this section is "tomato puree" or alternatively "tomato pulp"; however, if the only optional tomato ingredient used is the ingredient specified in paragraph (a) (1) of this section and the food contains not less than 20.0 percent of natural tomato soluble solids, the name "concentrated tomato juice" may be used in lieu of the names "tomato puree" or "tomato pulp".

(3) Wherever the name "Tomato puree" or "Tomato pulp" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement or statements specified in this section, showing the optional ingredients present, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 155.194 Catsup.

(a) Catsup, ketchup, catchup, is the food prepared from one or any combination of two or all of the following optional ingredients:

(1) The liquid obtained from mature tomatoes of red or reddish varieties.

(2) The liquid obtained from the residue from preparing such tomatoes for canning, consisting of peelings and cores with or without such tomatoes or pieces thereof.

(3) The liquid obtained from the residue from partial extraction of juice from such tomatoes.

Such liquid is obtained by so straining such tomatoes or residue, with or without heating, as to exclude skins, seeds, and other coarse or hard substances. Prior to straining, food-grade hydrochloric acid may be added to the tomato material at a rate to obtain a pH no lower than 2.0±0.2. Such acid is then neutralized with food-grade sodium hydroxide so that the treated tomato material is restored to a pH of 4.2±0.2, prior to straining. It is concentrated and seasoned with salt (sodium chloride formed during acid neutralization shall be considered added salt), a vinegar or vinegars, spices or flavorings or both, and onions or garlic or both, and is sweetened with sugar, or dextrose, or corn sirup (including dried corn sirup), or glucose sirup (including dried glucose sirup), or any mixture of these; provided that when the solids of corn sirup, or dried corn sirup, or glucose sirup, or dried glucose sirup (or any combination of these) used contains less than 58 percent by weight of reducing sugars calculated as anhydrous dextrose, then such corn sirup or glucose sirup shall be mixed with sugar or dextrose or both, in such quantity that the weight of the solids of such corn sirup or dried corn sirup or both, or glucose sirup, or dried glucose sirup or both, is not more than one-third of the weight of the solids of such mixture. When sealed in a container, it is so processed by heat, before or after sealing, as to prevent spoilage.

(b) (1) For the purposes of this section, the term "corn sirup" means refined corn sirup (including dried corn sirup) the solids of which contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose.

(2) The term "glucose sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of glucose sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose. "Dried glucose sirup" means the product obtained by drying "glucose sirup."

(c) When optional ingredient specified in paragraph (a) (2) of this section, is present, in whole or in part, the label shall bear the statement "Made from _____" (or "Made in part from _____", as the case may be) "Residual tomato material from canning". When optional ingredient specified in paragraph (a) (3) of this section is present, in whole or in part, the label shall bear the statement "Made from _____" (or "Made in part from _____", as the case may be) "Residual tomato material from partial extraction of juice". If both such ingredients are present, such statements may be combined in the statement "Made from _____" (or "Made in part from _____", as the case may be) "Residual tomato material from canning and from partial extraction of juice". Wherever the name "Catsup", "Ketchup" or "Catchup" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement or statements specified in this paragraph showing the optional ingredients present shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 155.200 Certain other canned vegetables.

(a) The canned vegetables for which definitions and standards of identity are prescribed by this section are those named in column I of the table set forth

[7] "Collaborative Study of the Determination of Soluble Solids in Tomato Products by Refractive Index Expressed as Percent Sucrose" by Frank C. Lamb, National Canners Association, 1950 Sixth Street, Berkeley, CA 94710, "Journal of the Association of Official Analytical Chemists," vol. 52, No. 5 (1969), pp. 1050–54. Adopted as official, first action at the 1969 AOAC meeting.

in paragraph (b) of this section. The vegetable ingredient in each such canned vegetable is obtained by proper preparation from the succulent vegetable prescribed in column II of such table. If two or more forms of such ingredient are designated in column III of such table, the vegetable in each such form is an optional ingredient. To the vegetable ingredient additional ingredients as required or permitted by paragraph (c) of this section are added, and the food is sealed in a container and so processed by heat as to prevent spoilage.

(b) The table referred to in paragraph (a) of this section is as follows:

I Name or synonym of canned vegetable	II Source	III Optional forms of vegetable ingredient
Artichokes	Flower buds of the artichoke plant	Whole; half or halves or halved; whole hearts; halved hearts; quartered hearts.
Asparagus	Edible portions of sprouts of the asparagus plant, as follows:	
	3 and ¾ in or more of upper end	Stalks or spears.
	3 and ¾ in or more of peeled upper end	Peeled stalks or peeled spears.
	Not less than 2 and ¾ in but less than 3 and ¾ in of upper end	Tips.
	Less than 2 and ¾ in of upper end	Points.
	Sprouts cut in pieces	Cut stalks or cut spears.
	Sprouts from which the tip has been removed, cut in pieces.	Bottom cuts or cuts—tips removed.
Bean sprouts	Sprouts of the Mung bean	
Shelled beans	Seed shelled from green or wax bean pods, with or without snaps (pieces of immature unshelled pods).	
Lima beans or butter beans	Seed shelled from the pods of the lima bean plant.	
Beets	Root of the beet plant	Whole; slices or sliced; quarters or quartered; dice or diced; cut; shoestring or French style or julienne.
Beet greens	Leaves, or leaves and immature root, of the beet plant.	
Broccoli	Heads of the broccoli plant	
Brussels sprouts	Sprouts of the brussels sprouts plant	
Cabbage	Cut pieces of the heads of the cabbage plant.	
Carrots	Root of the carrot plant	Do.
Cauliflower	Cut pieces of the head of the cauliflower plant.	
Celery	Stalks of the celery plant	Cut; hearts.
Collards	Leaves of the collard plant	
Dandelion greens	Leaves of the dandelion plant	
Kale	Leaves of the kale plant	
Mushrooms	Cap and stem of the mushroom	Buttons; whole, slices or sliced; pieces and stems.
Mustard greens	Leaves of the mustard plant	
Okra	Pods of the okra plant	Whole; cut.
Onions	Bulb of the onion plant	Do.
Parsnips	Root of the parsnip plant	Whole; quarters or quartered; slices or sliced; cut; shoestring or French style or julienne.
Black-eye peas or black-eyed peas.	Seed shelled from pods of the black-eye pea plant, with or without snaps (pieces of immature unshelled pods).	
Field peas	Seed shelled from pods of the field pea plant (other than the black-eye pea plant), with or without snaps (pieces of immature unshelled pods).	
Green sweet peppers	Green pods of the sweet pepper plant	Whole, halves or halved, pieces; dice or diced; strips; chopped.
Red sweet peppers	Red-ripe pods of the sweet pepper plant	Do.
Pimientos or pimentos	Red-ripe pods of the pimiento, pimento, pepper plant.	Whole, halves or halved; pieces; dice or diced; slices or sliced; chopped.
Potatoes	Tuber of the potato plant.	Whole; slices or sliced; dice or diced; pieces; shoestring or French style or julienne; French fry cut.
Rutabagas	Root of the rutabaga plant	Whole; quarters or quartered; slices or sliced; dice or diced; cut.
Salsify	Root of the salsify plant	
Spinach	Leaves of the spinach plant	Whole leaf; cut leaf or sliced; chopped.
Sweetpotatoes	Tuber of the sweetpotato plant	Whole; mashed; pieces or cuts or cut (longitudinally cut halves may be named on labels as halves or halved in lieu of pieces or cuts or cut).
Swiss chard	Leaves of the Swiss chard plant	
Truffles	Fruit of the truffle	
Turnip greens	Leaves of the turnip plant	
Turnips	Root of the turnip plant	Whole; quarters or quartered; slices or sliced; dice or diced; cut.

(c) Water is added to the vegetable ingredient, except that pimientos may be canned with or without added water, and sweet potatoes in mashed form are canned without added water. Asparagus may be canned with added water, asparagus juice, or a mixture of both. For the purposes of this section, asparagus juice is the clear, unfermented liquid expressed from the washed and heated sprouts or parts of sprouts of the asparagus plant, and mixtures of asparagus juice and water are considered to be water when such mixtures are used as a packing medium for canned asparagus. In the case of artichokes, a vinegar or any safe and suitable organic acid, which either is not a food additive as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act, or if it is a food additive as so defined, is used in conformity with regulations established pursuant to section 409 of the act, is added in such quantity as to reduce the pH of the finished canned vegetable to 4.5 or below. The following optional ingredients, in the case of the vegetables specified, may be added:

(1) An edible vegetable oil, in the cases of artichokes and pimientos.

(2) Snaps, in the cases of shelled beans, black-eyed peas, and field peas.

(3) In the case of all vegetables (except canned mushrooms and except canned mashed sweetpotatoes as regards the seasonings lised in paragraph (c)(3)(iii) of this section) one or more of the following optional seasoning ingredients may be added in a quantity sufficient to season the food.

(i) Refined sugar (sucrose).

(ii) Refined corn sugar (dextrose).

(iii) Corn sirup, glucose sirup.

(iv) Dried corn sirup, dried glucose sirup.

(v) Spice.

(vi) A vinegar.

(vii) Green peppers or red peppers which may be dried.

(viii) Mint leaves.

(ix) Onions, which may be dried.

(x) Garlic, which may be dried.

(xi) Horseradish.

(xii) Lemon juice or concentrated lemon juice.

(xiii) Butter or margarine in a quantity not less than 3 percent by weight of the finished food. When butter or margarine is added, safe and suitable emulsifiers or stabilizers, or both, may be added. When butter or margarine is added, no spice or flavoring simulating the color or flavor imparted by butter or margarine is used.

(4) In the case of all vegetables, the following optional ingredients may be added:

(i) Salt.

(ii) Monosodium glutamate.

(iii) Disodium inosinate complying with the provisions of § 172.535 of this chapter.

(iv) Disodium guanylate complying with the provisions of § 172.530 of this chapter.

(v) Hydrolyzed vegetable protein.

(vi) Autolyzed yeast extract.

(5) In the case of all vegetables except canned mushrooms, flavoring (except artificial) may be added.

(6)(i) In the case of potatoes, purified calcium chloride, calcium sulfate, calcium citrate, monocalcium phosphate, or any mixture of two or more such calcium salts, in a quantity reasonably necessary to firm the potatoes, but in no case in a quantity such that the calcium contained in any such salt or mixture is more than 0.1 percent of the weight of the finished food.

(ii) In the case of green sweet peppers, red sweet peppers, or lima beans, purified calcium chloride, calcium sulfate, calcium citrate, monocalcium phosphate, or any mixture of two or more such calcium salts, in a quantity reasonably necessary to firm the peppers or lima beans, but in no case in a quantity such that the calcium contained in such calcium salt or mixture is more than 0.026 percent of the weight of the finished food.

(iii) In the case of canned bean sprouts, calcium lactate may be added in an amount reasonably necessary to im-

prove crispness but not in an amount such that calcium contained therein exceeds 0.051 percent of the weight of the finished food.

(iv) In the case of carrots, purified calcium chloride, calcium sulfate, calcium citrate, monocalcium phosphate, or any mixture of two or more such calcium salts, in a quantity reasonably necessary to firm the carrots, but in no case in a quantity such that the calcium contained in any such salt or mixture is more than 0.036 percent by weight of the finished food.

(7) In the case of canned mushrooms, ascorbic acid (vitamin C) may be added in a quantity not to exceed 37.5 milligrams for each ounce of drained weight of mushrooms.

(8) In the case of canned artichokes packed in glass containers, ascorbic acid may be added in a quantity not to exceed 32 milligrams per 100 grams of the finished food.

(9) In the case of canned asparagus packed in glass containers, stannous chloride may be added in a quantity not to exceed 15 parts per million calculated as tin (Sn), except that in the case of asparagus packed in glass containers with lids lined with an inert material the quantity of stannous chloride added may exceed 15 parts per million but not 20 parts per million calculated as tin (Sn).

(10) In the case of canned black-eyed peas, disodium EDTA may be added in a quantity not to exceed 145 parts per million.

(11) In the case of potatoes, calcium disodium EDTA may be added in a quantity not to exceed 110 parts per million.

(12) A vinegar or any safe and suitable organic acid, which either is not a food additive as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act, or if it is a food additive as so defined, is used in conformity with regulations established pursuant to section 409 of the act, in the cases of all vegetables (except artichokes, in which the quantity of such optional ingredient is prescribed by the introductory text of paragraph (c) of this section, and except canned mushrooms, in which no such ingredient is permitted), in a quantity which, together with the amount of any lemon juice or concentrated lemon juice that may be added, is not more than sufficient to permit effective processing by heat without discoloration or other impairment of the article.

(d) The name of each canned vegetable for which a definition and standard of identity is prescribed by this section is the name or any synonym thereof whereby such vegetable is designated in column I of the table in paragraph (b) of this section.

(e) When two or more forms of the vegetable are specified in column III of the table in paragraph (b) of this section, the label shall bear the specified word or words, or in case synonyms are so specified, one of such synonyms, showing the form of the vegetable ingredient present; except that in the case of canned spinach, if the whole leaf is the optional form used, the word "spinach" unmodified may be used in lieu of the words "whole leaf spinach".

(f) (1) If the optional ingredient specified in paragraph (c) (1) of this section is present, the label shall bear the statement "_____ oil added" or "With added _____ oil", the blank being filled in with the common or usual name of the oil.

(2) If asparagus juice is used as a packing medium in canned asparagus, the label shall bear the statement "Packed in asparagus juice".

(3) If the optional ingredient specified in paragraph (c) (2) of this section is present, the label shall bear the statement "With snaps".

(g) The name of the food shall include a declaration of any flavoring that characterizes the product as specified in § 101.122 of this chapter, and a declaration of any spice or seasoning that characterizes the product; for example, "with added spice", "seasoned with red peppers", "seasoned with butter". Wherever the name of the vegetable appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements specified in paragraphs (e) and (f) (1) through (3) of this section shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter, except that the varietal name of the vegetable may so intervene.

(h) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 155.201 Canned mushrooms.

(a) *Identity.* The standard of identity for canned mushrooms is part of the standard of identity for certain other canned vegetables under § 155.200.

(b) [Reserved]

(c) *Fill of container.* The standard of fill of container for canned mushrooms is a fill such that:

(1) The weight of drained mushrooms in a container the dimensions of which are specified in the following table is not less than the weight of drained mushrooms prescribed in such table for such container:

Trade designation	Overall dimensions sealed can (inches)		Weight in ounces of drained mushrooms (avoirdupois)
	Diameter	Height	
202 x 204	2 1/16	2 1/4	3
211 x 212	2 13/16	2 3/4	8
300 x 400	3	4	4
307 x 510	3 1/16	5 5/16	16
603 x 700	6 3/16	7	68

(2) The drained weight of mushrooms in containers of a size not specified in paragraph (c) (1) of this section is not less than 56 percent of the water capacity of the container, if such water capacity is less than 11.0 ounces avoirdupois; not less than 59 percent of the water capacity of the container, if such water capacity is 11.0 ounces or more but less than 25 ounces avoirdupois; and not less than 62 percent of the water capacity of the container, if such water capacity is 25 ounces avoirdupois or more.

(3) Water capacity of containers is determined by the general method provided in § 130.12 of this chapter.

(4) Drained weight is determined by the following method: Tilt the opened container so as to distribute the contents evenly over the meshes of a circular sieve which has been previously weighed. The diameter of the sieve is 8 inches if the quantity of contents of the container is less than 3 pounds, and 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is woven-wire cloth which complies with the specifications for such cloth set forth under "2380 Micron (No. 8)" in table I of "Standard Specifications for Sieves," published March 1, 1940, in L.C. 584 of the U.S. Department of Commerce, National Bureau of Standards. Without shifting the material on the sieve, so incline the sieve as to facilitate drainage. Two minutes after drainage begins, weigh the sieve and drained mushrooms. The weight so found, less the weight of the sieve, shall be considered to be the weight of drained mushrooms.

(5) If canned mushrooms fall below the applicable standard of fill of container prescribed in paragraph (c) (1) or (2) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

PART 156—VEGETABLE JUICES

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Vegetable Juices

Sec.

156.145 Tomato juice.
156.147 Yellow tomato juice.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046 as amended, 1055–1056 as amended (21 U.S.C. 341, 371).

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Vegetable Juices

§ 156.145 Tomato juice.

(a) Tomato juice is the unconcentrated liquid extracted from mature tomatoes of red or reddish varieties, with or without scalding followed by draining. In the extraction of such liquid, heat may be applied by any method which does not add water thereto. Such liquid is strained free from skins, seeds, and other coarse or hard substances, but carries finely divided insoluble solids from the flesh of the tomato. Such liquid may be homogenized, and may be seasoned with salt. Such liquid may contain added ascorbic acid in a quantity such that the total vitamin C in each fluid ounce of the finished food is 10 milligrams as determined by the method prescribed in sections 39.051–39.055 of the Official Methods of Analysis of the Association of Official Analytical Chemists, 11th ed., 1970, pp. 777–778, under "Vita-

min C (Ascorbic Acid) Official Final Action".[2] When sealed in a container, it is so processed by heat, before or after sealing, as to prevent spoilage.

(b) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter. Tomato juice to which vitamin C has been added may bear on its label the statement "Enriched with Vitamin C" in accordance with § 104.5 of this chapter or "with added vitamin C" or a similar statement.

EFFECTIVE DATE NOTE: At 39 FR 20684, June 14, 1974, § 156.145 (formerly § 53.1) was revised. At 39 FR 31898, Sept. 3, 1974, the effective date was stayed pending a public hearing. For the convenience of the user the currently effective section follows:

§ 156.145 Tomato juice; identity.

Tomato juice is the unconcentrated liquid extracted from mature tomatoes of red or reddish varieties, with or without scalding followed by draining. In the extraction of such liquid, heat may be applied by any method which does not add water thereto. Such liquid is strained free from skins, seeds, and other coarse or hard substances, but carries finely divided insoluble solids from the flesh of the tomato. Such liquid may be homogenized, and may be seasoned with salt. When sealed in a container it is so processed by heat, before or after sealing, as to prevent spoilage.

§ 156.147 Yellow tomato juice.

Yellow tomato juice is the unconcentrated liquid extracted from mature tomatoes of yellow varieties. It conforms, in all other respects, to the definition and standard of identity for tomato juice prescribed in § 156.145.

PART 158—FROZEN VEGETABLES

Subpart A—General Provisions

Sec.
158.3 Definitions.

Subpart B—Requirements for Specific Standardized Frozen Vegetables

158.170 Frozen peas.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046 as amended, 1055–1056, as amended (21 U.S.C. 341, 371).

Subpart A—General Provisions

§ 158.3 Definitions.

For the purposes of this part the following definitions shall apply:

(a) *Lot.* A collection of primary containers or units of the same size, type and style manufactured or packed under similar conditions and handled as a single unit of trade.

(b) *Lot size.* The number of primary containers or units (pounds when in bulk) in the lot.

(c) *Sample size.* The total number of sample units drawn for examination from a lot.

(d) *Sample unit.* A container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for the examination or testing as a single unit.

(e) *Defective.* Any sample unit shall be regarded as defective when the sample unit does not meet the criteria set forth in the standards.

(f) *Acceptance number.* The maximum number of defective sample units permitted in the sample in order to consider the lot as meeting the specified requirements. The following acceptance numbers shall apply:

Lot size (primary container)	Size container	
	Net weight equal to or less than 1 kg (2.2 lb)	
	n	c
4,800 or less	13	2
4,801 to 24,000	21	3
24,001 to 48,000	29	4
48,001 to 84,000	48	6
84,001 to 144,000	84	9
144,001 to 240,000	126	13
Over 240,000	200	19
	Net weight greater than 1 kg (2.2 lb)	
	n	c
Number of pounds:		
20,000 or less	13	2
More than 20,000 to 100,000	21	3
More than 100,000 to 200,000	29	4
More than 200,000 to 400,000	48	6
More than 400,000 to 600,000	84	9
More than 600,000 to 1,000,000	126	13
More than 1,000,000	200	19

n=number of sample units.
c=acceptance number.

(g) *Acceptable quality level (AQL).* The maximum percent of defective sample units permitted in a lot that will be accepted approximately 95 percent of the time.

Subpart B—Requirements for Specific Standardized Frozen Vegetables

§ 158.170 Frozen peas.

(a) *Identity*—(1) *Product definition.* Frozen peas is the food in "package" form as that term is defined in § 1.1(b) of this chapter, prepared from the succulent seed of the pea plant of the species *Pisum sativum* L. Any suitable variety of pea may be used. It is blanched, drained, and preserved by freezing in such a way that the range of temperature of maximum crystallization is passed quickly. The freezing process shall not be regarded as complete until the product temperature has reached −18° C (0° F) or lower at the thermal center, after thermal stabilization. Such food may contain one, or any combination of two or more, of the following safe and suitable optional ingredients:

(i) Natural and artificial flavors.

(ii) Condiments such as spices and mint leaves.

(iii) Dry nutritive carbohydrate sweeteners.

(iv) Salt.

(v) Monosodium glutamate and other glutamic acid salts.

(2) *Size specifications.* If size graded, frozen peas shall contain not less than 80 percent by weight of peas of the size declared or of smaller sizes. The sample unit may not contain more than 20 percent by weight of peas of the next two larger sizes, of which not more than one quarter by weight of such peas may be of the larger of these two sizes, and may contain no peas larger than the next two larger sizes, if such there be. The following sizes and designations shall apply:

	Round hole sieve size through which peas will pass	
	Millimeters	*Inch*
Size designation:		
Extra small	Up to 7.5	0.295
Very small	Up to 8.2	.32
Small	Up to 8.75	.34
Medium	Up to 10.2	.40
Large	Over 10.2	.40

(3) *Labeling.* The name of the product is "peas". The term "early", "June", or "early June" shall precede or follow the name in the case of smooth-skin or substantially smooth-skin peas, such as Alaska-type peas. Where the peas are of sweet green wrinkled varieties, the name may include the designation "sweet", "green", "wrinkled", or any combination thereof. The label shall contain the words "frozen" or "quick frozen". The name of the food shall include a declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any condiment such as spices and mint leaves that characterizes the product, e.g., "Spice added". Where a statement of pea size is made, such statement shall indicate either the size designation as specified in paragraph (a)(2) of this section or the applicable sieve size. However, the optional descriptive words "petite" or "tiny" may be used in conjunction with the product name when an average of 80 percent or more of the peas will pass through a circular opening of a diameter of 8.75 mm (0.34 in) or less for sweet green wrinkled peas and 8.2 mm (0.32 in) for smooth-skin or substantially smooth-skin peas, such as Alaska-type peas.

(4) *Ingredient statement.* The name of each of the ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(b) *Quality*—(1) The standard of quality for frozen peas is as follows:

(i) Not more than 4 percent by weight blond peas, i.e., yellow or white but edible peas;

(ii) Not more than 10 percent by weight blemished peas, i.e., slightly stained or spotted peas;

(iii) Not more than 2 percent by weight seriously blemished peas, i.e., peas that are hard, shrivelled, spotted, discolored or otherwise blemished to an extent that the appearance or eating quality is seriously affected;

(iv) Not more than 15 percent by weight pea fragments, i.e., portions of peas, separated or individual cotyledons, crushed, partial or broken cotyledons and loose skins, but excluding entire intact peas with skins detached;

(v) Not more than 0.5 percent by weight, or more than 12 sq cm (2 sq in)

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in area, extraneous vegetable material, i.e., vine or leaf or pod material from the pea plant or other such material per sample unit as defined in paragraph (b) of this section.

(vi) The sum of the pea material described in paragraph (b)(1)(i), (ii), (iii) and (iv) of this section shall not exceed 15 percent.

(vii) For peas that meet the organoleptic and analytical characteristics of sweet green wrinkled varieties:

(*a*) The alcohol-insoluble solids may not be more than 19 percent based on the procedure set forth in paragraph (b)(3) of this section.

(*b*) Not more than 15 percent by count of the peas may sink in a solution containing 16 percent salt by weight according to the brine flotation test set forth in paragraph (b)(4) of this section;

(viii) For smooth-skin or substantially smooth-skin varieties the alcohol insoluble solids may not be more than 23 percent based on the procedure set forth in paragraph (b)(3) of this section.

(ix) The quality of a lot shall be considered acceptable when the number of defectives does not exceed the acceptance number in the sampling plans set forth in § 158.3(f).

(2) The sample unit for determining compliance with the requirements of paragraph (b)(1) of this section other than those of paragraphs (b)(1)(vii)(*a*) and (b)(1)(viii) of this section, shall be 500 g (17.6 oz). For the determination of alcohol-insoluble solids as specified in paragraph (b)(3) of this section, the container may be the sample unit.

(3) Alcohol-insoluble solids determination.

(i) Extracting solutions:

(*a*) One hundred parts of ethanol denatured with five parts of methanol volume to volume (formula 3A denatured alcohol), or

(*b*) A mixture of 95 parts of formula 3A denatured alcohol and five parts of isopropanol v/v.

(ii) Eighty percent alcohol (8 liters of extracting solutions, specified in paragraph (b)(3)(i) (*a*) or (*b*) of this section, diluted to 9.5 liters with water).

(iii) Drying dish—a flat-bottom dish with a tight fitting cover.

(iv) Drying oven—a properly ventilated oven thermostatically controlled at 100±2° C.

(v) Procedure—Transfer frozen contents of package to plastic bag; tie bag securely and immerse in water bath with continuous flow at room temperature. Avoid agitation of bag during thawing by using clamps or weights. When sample completely thaws, remove bag, blot off adhering water, and transfer peas to U.S. No. 8 sieve, using (20 cm.) size for container of less than 3 lb. net weight and (30.5 cm.) for larger quantities. Without shifting peas, incline sieve to aid drainage, drain 2 minutes. With cloth wipe surplus water from lower screen surface. Weigh 250 g. of peas into high-speed blender, add 250 g. of water and blend to smooth paste. For less than 250 g. sample, use entire sample with equal weight of water. Weight 20 g. ±10 mg. of the paste into 250 ml. distillation flask, add 120 ml. of extracting solutions specified in paragraph (b)(3)(i) (*a*) or (*b*) of this section, and reflux 30 minutes on steam or water bath or hotplate. Fit into a buchner funnel a filter paper of appropriate size (previously prepared by drying in flatbottom dish for 2 hours in drying oven, covering, cooling in desiccator, and weighing). Apply vacuum to buchner funnel and transfer contents of beaker so as to avoid running over edge of paper. Aspirate to dryness and wash material on filter with 80 percent alcohol until washings are clear and colorless. Transfer paper and alcohol-insoluble solids to drying dish used to prepare paper, dry uncovered for 2 hours in drying oven, cover, cool in desiccator, and weigh at once. From this weight deduct weight of dish, cover, and paper. Calculate percent by weight of alcohol-insoluble solids.

(4) Brine flotation test. (i) Explanation—The brine flotation test utilizes salt solutions of various specific gravities to separate the peas according to maturity. The brine solutions are based on the percentage by weight of pure salt (NaCl) in solution at 20° C. In making the test the brine solutions are standardized to the proper specific gravity equivalent to the specified "percent of salt solutions at 20° C" by using a salometer spindle accurately calibrated at 20° C. A 250 ml. glass beaker or similar receptacle is filled with the brine solution to a depth of approximately 50 mm. The brine solution and sample (100 peas per container) must be at the same temperature and should closely approximate 20° C.

(ii) Procedure—After carefully removing the skins from the peas, place the peas into the solution. Pieces of peas and loose skins should not be used in making the brine flotation test. If cotyledons divide, use both cotyledons in the test and consider the two separated cotyledons as 1 pea; and, if an odd cotyledon sinks, consider it as one pea. Only peas that sink to the bottom of the receptacle within 10 seconds after immersion are counted as "peas that sink".

(5) If the quality of the frozen peas falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in the Code of Federal Regulations but in lieu of the words prescribed in the second line of the rectangle the following words may be used where the frozen peas fall below the standard in only one respect: "Below standard in quality _____", the blank to be filled in with the specific reason for substandard quality as listed in the standard.

PART 160—EGGS AND EGG PRODUCTS

Subpart A—[Reserved]

Subpart B—Requirements for Specific Eggs and Egg Products

Sec.
160.100 Eggs.
160.105 Dried eggs.
160.110 Frozen eggs.
160.115 Liquid eggs.
160.140 Egg whites.
160.145 Dried egg whites.
160.150 Frozen egg whites.
160.180 Egg yolks.
160.185 Dried egg yolks.
160.190 Frozen egg yolks.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046, as amended, 1055–1056, as amended (21 U.S.C. 341, 371) unless otherwise noted.

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Eggs and Egg Products

§ 160.100 Eggs.

No regulation shall be promulgated fixing and establishing a reasonable definition and standard of identity for the food commonly known as eggs.

§ 160.105 Dried eggs.

(a) Dried eggs, dried whole eggs are prepared by drying liquid eggs that conform to § 160.115, with such precautions that the finished food is free of viable *Salmonella* microorganisms. They may be powdered. Before drying, the glucose content of the liquid eggs may be reduced by one of the optional procedures set forth in paragraph (b) of this section. Either silicon dioxide complying with the provisions of § 172.480 of this chapter or sodium silicoaluminate may be added as an optional anticaking ingredient, but the amount of silicon dioxide used is not more than 1 percent and the amount of sodium silicoaluminate used is less than 2 percent by weight of the finished food. The finished food shall contain not less than 95 percent by weight total egg solids.

(b) The optional glucose-removing procedures are:

(1) *Enzyme procedure.* A glucose-oxidase-catalase preparation and hydrogen peroxide solution are added to the liquid eggs. The quantity used and the time of reaction are sufficient to substantially reduce the glucose content of the liquid eggs. The glucose-oxidase-catalase preparation used is one that is generally recognized as safe within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act. The hydrogen peroxide solution used shall comply with the specifications of the United States Pharmacopeia, except that it may exceed the concentration specified therein and it does not contain a preservative.

(2) *Yeast procedure.* The pH of the liquid eggs is adjusted to the range of 6.0 to 7.0, if necessary, by the addition of dilute, chemically pure hydrochloric acid, and controlled fermentation is maintained by adding food-grade baker's yeast (*Saccharomyces cerevisiae*). The quantity of yeast used and the time of reaction are sufficient to substantially reduce the glucose content of the liquid eggs.

(c) The name of the food for which a definition and standard of identity is prescribed by this section is "Dried eggs" or "Dried whole eggs" and if the glucose content was reduced, as provided in paragraph (b) of this section, the name shall be followed immediately by the statement "Glucose removed for stability" or "Stabilized, glucose removed".

(d) (1) When either of the optional anticaking ingredients specified in paragraph (a) of this section is used, the label shall bear the statement "Not more than 1 percent silicon dioxide added as an anticaking agent" or "Less than 2 percent sodium silicoaluminate added as an anticaking agent", whichever is applicable.

(2) The name of any optional ingredient used, as provided in paragraph (d) (1) of this section, shall be listed on the principal display panel or panels of the label with such prominence and conspicuousness as to render such statement likely to be read and understood by the ordinary individual under customary conditions of purchase.

§ 160.110 Frozen eggs.

(a) Frozen eggs, frozen whole eggs, frozen mixed eggs is the food prepared by freezing liquid eggs that conform to § 160.115, with such precautions that the finished food is free of viable *Salmonella* microorganisms.

(b) Monosodium phosphate or monopotassium phosphate may be added either directly or in a water carrier, but the amount added does not exceed 0.5 percent of the weight of the frozen eggs. If a water carrier is used, it shall contain not less than 50 percent by weight of such monosodium phosphate or monopotassium phosphate.

(c) When one of the optional ingredients specified in paragraph (b) of this section is used, the label shall bear the statement "Monosodium phosphate (or monopotassium phosphate) added to preserve color", or, in case the optional ingredient used is added in a water carrier, the statement shall be "Monosodium phosphate (or monopotassium phosphate), with _____ percent water as a carrier, added to preserve color", the blank being filled in to show the percent by weight of water used in proportion to the weight of the finished food. The statement declaring the optional ingredient used shall appear on the principal display panel or panels with such prominence and conspicuousness as to render it likely to be read and understood under customary conditions of purchase.

§ 160.115 Liquid eggs.

Liquid eggs, mixed eggs, liquid whole eggs, mixed whole eggs are eggs of the domestic hen broken from the shells and with yolks and whites in their natural proportion as so broken. They may be mixed, or mixed and strained, and they are pasteurized or otherwise treated to destroy all viable *Salmonella* microorganisms. Pasteurization or such other treatment is deemed to permit the adding of safe and suitable substances (other than chemical preservatives) that are essential to the method of pasteurization or other treatment used. For the purposes of this paragraph, safe and suitable substances are those that perform a useful function in the pasteurization or other treatment to render the liquid eggs free of viable *Salmonella* microorganisms, and that are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act; or, if they are food additives, they are used in conformity with regulations established pursuant to section 409 of the act.

§ 160.140 Egg whites.

(a) Egg whites, liquid egg whites, liquid egg albumen is the food obtained from eggs of the domestic hen, broken from the shells and separated from yolks. The food may be mixed, or mixed and strained, and is pasteurized or otherwise treated to destroy all viable *Salmonella* microorganisms. Pasteurization or such other treatment is deemed to permit the adding of safe and suitable substances (other than chemical preservatives) that are essential to the method of pasteurization or other treatment used. Safe and suitable substances that aid in protecting or restoring the whipping properties of liquid egg whites may be added. For the purposes of this paragraph, safe and suitable substances are those that perform a useful function as whipping aids or in the pasteurization or other treatment to render liquid egg whites free of viable *Salmonella* microorganisms and that are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act; or, if they are food additives, they are used in conformity with regulations established pursuant to section 409 of the act.

(b) Any optional ingredients used as whipping aids, as provided for in paragraph (a) of this section, shall be named on the principal display panel or panels of labels with such prominence and conspicuousness as to render such names likely to be read and understood by ordinary individuals under customary conditions of purchase.

§ 160.145 Dried egg whites.

(a) The food dried egg whites, egg white solids, dried egg albumen, egg albumen solids is prepared by drying liquid egg whites conforming to the requirements of § 160.140 (or deviating from that section only by not being *Salmonella* free). As a preliminary step to drying, the glucose content of the liquid egg whites is reduced by adjusting the pH, where necessary, with food-grade acid and by following one of the optional procedures set forth in paragraph (b) of this section. If the food is prepared from liquid egg whites conforming in all respects to the requirements of § 160.140, drying shall be done with such precautions that the finished food is free of viable *Salmonella* microorganisms. If the food is prepared from liquid egg whites that are not *Salmonella* free, the dried product shall be so treated by heat or otherwise as to render the finished food free of viable *Salmonella* microorganisms. Dried egg whites may be powdered.

(b) The optional glucose-removing procedures are:

(1) *Enzyme procedure.* A glucose-oxidase-catalase preparation and hydrogen peroxide solution are added to liquid egg whites. The quantity used and the time of reaction are sufficient to substantially reduce the glucose content. The glucose-oxidase-catalase preparation used is one that is generally recognized as safe within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act. The hydrogen peroxide solution used shall comply with the specifications of the United States Pharmacopeia, except that it may exceed the concentration specified therein and it does not contain a preservative.

(2) *Controlled fermentation procedures*—(i) *Yeast procedure.* Food-grade baker's yeast (*Saccharomyces cerevisiae*) is added to the liquid egg whites and controlled fermentation is maintained. The quantity of yeast used and the time of reaction are sufficient to substantially reduce the glucose content.

(ii) *Bacterial procedure.* The liquid egg whites are subjected to the action of a culture of glucose-fermenting bacteria either generally recognized as safe within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act or the subject of a regulation established pursuant to section 409 of the act, and the culture is used in conformity with such regulation. The quantity of the culture used is sufficient to predominate in the fermentation and the time and temperature of reaction are sufficient to substantially reduce the glucose content.

(c) When the dried egg whites are prepared from liquid egg whites containing any optional ingredients added as whipping aids, as provided for in § 160.140(a), the common names of such optional ingredients shall be listed on the principal display panel or panels of the label with such prominence and conspicuousness as to render the names likely to be read and understood by ordinary individuals under customary conditions of purchase.

§ 160.150 Frozen egg whites.

(a) Frozen egg whites, frozen egg albumen is the food prepared by freezing liquid egg whites that conform to § 160.140, with such precautions that the finished food is free of viable *Salmonella* microorganisms.

(b) When frozen egg whites are prepared from liquid egg whites containing any optional ingredients added as whipping aids, as provided for in § 160.140(a), the common names of such optional ingredients shall be listed on the principal display panel or panels of the label with such prominence and conspicuousness as to render such names likely to be read and understood by ordinary individuals under customary conditions of purchase.

§ 160.180 Egg yolks.

Egg yolks, liquid egg yolks, yolks, liquid yolks are yolks of eggs of the domestic hen, so separated from the whites thereof as to contain not less than 43 percent total egg solids, as determined by the method prescribed in "Official Methods of Analysis of the Association of Official Agricultural Chemists," 10th edition, 1965, p. 257, sections 16.002 and 16.003, under "Total Solids." They may be

mixed, or mixed and strained, and they are pasteurized or otherwise treated to destroy all viable *Salmonella* microorganisms. Pasteurization or such other treatment is deemed to permit the adding of safe and suitable substances (other than chemical preservatives) that are essential to the method of pasteurization or other treatment used. For the purposes of this paragraph, safe and suitable substances are those that perform a useful function in the pasteurization or other treatment to render the egg yolks free of viable *Salmonella* microorganisms, and that are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act; or, if they are food additives, they are used in conformity with regulations established pursuant to section 409 of the act.

§ 160.185 Dried egg yolks.

(a) Dried egg yolks, dried yolks is the food prepared by drying egg yolks that conform to § 160.180, with such precautions that the finished food is free of viable *Salmonella* microorganisms. Before drying, the glucose content of the liquid egg yolks may be reduced by one of the optional procedures set forth in paragraph (b) of this section. Either silicon dioxide complying with the provisions of § 172.480 of this chapter or sodium silicoaluminate may be added as an optional anticaking ingredient, but the amount of silicon dioxide used is not more than 1 percent and the amount of sodium silicoaluminate used is less than 2 percent by weight of the finished food. The finished food shall contain not less than 95 percent by weight total egg solids.

(b) The optional glucose-removing procedures are:

(1) *Enzyme procedure.* A glucose-oxidase-catalase preparation and hydrogen peroxide solution are added to the liquid egg yolks. The quantity used and the time of reaction are sufficient to substantially reduce the glucose content of the liquid egg yolks. The glucose-oxidase-catalase preparation used is one that is generally recognized as safe within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act. The hydrogen peroxide solution used shall comply with the specification of the United States Pharmacopeia, except that it may exceed the concentration specified therein and it does not contain a preservative.

(2) *Yeast procedure.* The pH of the liquid egg yolks is adjusted to the range of 6.0 to 7.0, if necessary, by the addition of dilute, chemically pure hydrochloric acid, and controlled fermentation is maintained by adding food-grade baker's yeast (*Saccharomyces cerevisiae*). The quantity of yeast used and the time of reaction are sufficient to substantially reduce the glucose content of the liquid egg yolks.

(c) The name of the food for which a definition and standard of identity is prescribed by this section is "Dried egg yolks", or "Dried yolks", and if the glucose content was reduced, as provided in paragraph (b) of this section, the name shall be followed immediately by the statement "Glucose removed for stability" or "Stabilized, glucose removed".

(d)(1) When either of the optional anticaking ingredients specified in paragraph (a) of this section is used, the label shall bear the statement "Not more than 1 percent silicon dioxide added as an anticaking agent" or "Less than 2 percent sodium silicoaluminate added as an anticaking agent", whichever is applicable.

(2) The name of any optional ingredient used, as provided in paragraph (d)(1) of this section, shall be listed on the principal display panel or panels of the label with such prominence and conspicuousness as to render such statement likely to be read and understood by the ordinary individual under customary conditions of purchase.

§ 160.190 Frozen egg yolks.

Frozen egg yolks, frozen yolks is the food prepared by freezing egg yolks that conform to § 160.180, with such precautions that the finished food is free of viable *Salmonella* microorganisms.

PART 161—FISH AND SHELLFISH

Subpart A—General Provisions

Sec.

161.30 Declaration of quantity of contents on labels for canned oysters.

Subpart B—Requirements for Specific Standardized Fish and Shellfish

161.130 Oysters.
161.131 Extra large oysters.
161.132 Large oysters.
161.133 Medium oysters.
161.134 Small oysters.
161.135 Very small oysters.
161.136 Olympia oysters.
161.137 Large Pacific oysters.
161.138 Medium Pacific oysters.
161.139 Small Pacific oysters.
161.140 Extra small Pacific oysters.
161.145 Canned oysters.
161.170 Canned Pacific salmon.
161.173 Canned wet pack shrimp and canned dry pack shrimp in nontransparent containers.
161.175 Frozen raw breaded shrimp.
161.176 Frozen raw lightly breaded shrimp.
161.190 Canned tuna.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046 as amended, 1055–1056 as amended (21 U.S.C. 341, 371) unless otherwise noted.

Subpart A—General Provisions

§ 161.30 Declaration of quantity of contents on labels for canned oysters.

(a) For many years packers of canned oysters in the Gulf area of the United States have labeled their output with a declaration of the drained weight of oysters in the containers. Packers in other areas have marketed canned oysters with a declaration of the total weight of the contents of the container. Investigation reveals that under present-day practice consumers generally do not discard the liquid packing medium, but use it as a part of the food. Section 403(e)(2) of the Federal Food, Drug, and Cosmetic Act and the regulations thereunder require food in package form to bear an accurate label statement of the quantity of food in the container.

(b) It is concluded that compliance with the label declaration of quantity of contents requirement will be met by an accurate declaration of the total weight of the contents of the can. The requirements of § 161.145(c), establishing a standard of fill of container for canned oysters and specifying the statement of substandard fill for those canned oysters failing to meet that standard remain unaffected by this interpretation.

(Sec. 403, 52 Stat. 1047, as amended; 21 U.S.C. 343)

Subpart B—Requirements for Specific Standardized Fish and Shellfish

§ 161.130 Oysters.

(a) Oysters, raw oysters, shucked oysters, are the class of foods each of which is obtained by shucking shell oysters and preparing them in accordance with the procedure prescribed in paragraph (b) of this section. The name of each such food is the name specified in the applicable definition and standard of identity, prescribed in §§ 161.131 to 161.140, inclusive.

(b) If water, or salt water containing less than 0.75 percent salt, is used in any vessel into which the oysters are shucked the combined volume of oysters and liquid when such oysters are emptied from such vessel is not less than four times the volume of such water or salt water. Any liquid accumulated with the oysters is removed. The oysters are washed, by blowing or otherwise, in water or salt water, or both. The total time that the oysters are in contact with water or salt water after leaving the shucker, including the time of washing, rinsing, and any other contact with water or salt water is not more than 30 minutes. In computing the time of contact with water or salt water, the length of time that oysters are in contact with water or salt water that is agitated by blowing or otherwise, shall be calculated at twice its actual length. Any period of time that oysters are in contact with salt water containing not less than 0.75 percent salt before contact with oysters, shall not be included in computing the time that the oysters are in contact with water or salt water. Before packing into the containers for shipment or other delivery for consumption the oysters are thoroughly drained and are packed without any added substance.

(c) For the purposes of this section:

(1) "Shell oysters" means live oysters of any of the species, *Ostrea virginica, Ostrea gigas, Ostrea lurida,* in the shell, which, after removal from their beds, have not been floated or otherwise held under conditions which result in the addition of water.

(2) "Thoroughly drained" means one of the following:

(i) The oysters are drained on a strainer or skimmer which has an area of not less than 300 square inches per gallon of oysters, drained, and has perforations of at least ¼ of an inch in diameter and not more than 1¼ inches

apart, or perforations of equivalent areas and distribution. The oysters are distributed evenly over the draining surface of the skimmer and drained for not less than 5 minutes; or

(ii) The oysters are drained by any method other than that prescribed by paragraph (c)(2)(i) of this section whereby liquid from the oysters is removed so that when the oysters are tested within 15 minutes after packing by draining a representative gallon of oysters on a skimmer of the dimensions and in the manner described in paragraph (c)(2)(i) of this section for 2 minutes, not more than 5 percent of liquid by weight is removed by such draining.

§ 161.131 Extra large oysters.

Extra large oysters, oysters counts (or plants), extra large raw oysters, raw oysters counts (or plants), extra large shucked oysters, shucked oysters counts (or plants), are of the species *Ostrea virginica* and conform to the definition and standard of identity prescribed for oysters by § 161.130 and are of such size that 1 gallon contains not more than 160 oysters and a quart of the smallest oysters selected therefrom contains not more than 44 oysters.

§ 161.132 Large oysters.

Large oysters, oysters extra selects, large raw oysters, raw oysters extra selects, large shucked oysters, shucked oysters extra selects, are of the species *Ostrea virginica* and conform to the definition and standard of identity prescribed for oysters by § 161.130 and are of such size that 1 gallon contains more than 160 oysters but not more than 210 oysters; a quart of the smallest oysters selected therefrom contains not more than 58 oysters, and a quart of the largest oysters selected therefrom contains more than 36 oysters.

§ 161.133 Medium oysters.

Medium oysters, oysters selects, medium raw oysters, raw oysters selects, medium shucked oysters, shucked oysters selects, are of the species *Ostrea virginica* and conform to the definition and standard of identity prescribed for oysters by § 161.130 and are of such size that 1 gallon contains more than 210 oysters, but not more than 300 oysters; a quart of the smallest oysters selected therefrom contains not more than 83 oysters, and a quart of the largest oysters selected therefrom contains more than 46 oysters.

§ 161.134 Small oysters.

Small oysters, oysters standards, small raw oysters, raw oysters standards, small shucked oysters, shucked oysters standards, are of the species *Ostrea virginica* and conform to the definition and standards of identity prescribed for oysters by § 161.130 and are of such size that 1 gallon contains more than 300 oysters but not more than 500 oysters; a quart of the smallest oysters selected therefrom contains not more than 138 oysters and a quart of the largest oysters selected therefrom contains more than 68 oysters.

§ 161.135 Very small oysters.

Very small oysters, very small raw oysters, very small shucked oysters are of the species *Ostrea virginica* and conform to the definition and standard of identity prescribed for oysters by § 161.130 and are of such size that 1 gallon contains more than 500 oysters, and a quart of the largest oysters selected therefrom contains more than 112 oysters.

§ 161.136 Olympia oysters.

Olympia oysters, raw Olympia oysters, shucked Olympia oysters, are of the species *Ostrea lurida* and conform to the definition and standard of identity prescribed for oysters in § 161.130.

§ 161.137 Large Pacific oysters.

Large Pacific oysters, large raw Pacific oysters, large shucked Pacific oysters, are of the species *Ostrea gigas* and conform to the definitions and standards of identity prescribed for oysters by § 161.130 and are of such size that 1 gallon contains not more than 64 oysters, and the largest oyster in the container is not more than twice the weight of the smallest oyster therein.

§ 161.138 Medium Pacific oysters.

Medium Pacific oysters, medium raw Pacific oysters, medium shucked Pacific oysters, are of the species *Ostrea gigas* and conform to the definition and standard of identity prescribed for oysters by § 161.130 and are of such size that 1 gallon contains more than 64 oysters and not more than 96 oysters, and the largest oyster in the container is not more than twice the weight of the smallest oyster therein.

§ 161.139 Small Pacific oysters.

Small Pacific oysters, small raw Pacific oysters, small shucked Pacific oysters, are of the species *Ostrea gigas* and conform to the definition and standard of identity prescribed for oysters by § 161.130 and are of such size that 1 gallon contains more than 96 oysters and not more than 144 oysters, and the largest oyster in the container is not more than twice the weight of the smallest oyster therein.

§ 161.140 Extra small Pacific oysters.

Extra small Pacific oysters, extra small raw Pacific oysters, extra small shucked Pacific oysters, are of the species *Ostrea gigas* and conform to the definition and standard of identity prescribed for oysters by § 161.130 and are of such size that 1 gallon contains more than 144 oysters, and the largest oyster in the container is not more than twice the weight of the smallest oyster therein.

§ 161.145 Canned oysters.

(a) *Identity*—(1) Canned oysters is the food prepared from one or any mixture of two or all of the forms of oysters specified in paragraph (a)(2) of this section, and a packing medium of water, or the watery liquid draining from oysters before or during processing, or a mixture of such liquid and water. The food may be seasoned with salt. It is sealed in containers and so processed by heat as to prevent spoilage.

(2) The forms of oysters referred to in paragraph (a)(1) of this section are prepared from oysters which have been removed from their shells and washed and which may be steamed while in the shell or steamed or blanched or both after removal therefrom, and are as follows:

(i) Whole oysters with such broken pieces of oysters as normally occur in removing oysters from their shells, washing, and packing.

(ii) Pieces of oysters obtained by segregating pieces of oysters broken in shucking, washing, or packing whole oysters.

(iii) Cut oysters obtained by cutting whole oysters.

(3)(i) When the form of oysters specified in paragraph (a)(2)(i) of this section is used, the name of the food is "Oysters" or "Cove oysters", if of the species *Ostrea virginica;* "Oysters" or "Pacific oysters", if of the species *Ostrea gigas;* "Oysters" or "Olympia oysters", if of the species *Ostrea lurida.*

(ii) When the form of oysters specified in paragraph (a)(2)(ii) of this section is used, the name of the food is "Pieces of _____", the blank being filled in with the name "Oysters" or "Cove oysters", if of the species *Ostrea virginica;* "Oysters" or "Pacific oysters", if of the species *Ostrea gigas;* "Oysters" or "Olympia oysters", if of the species *Ostrea lurida.*

(iii) When the form of oysters specified in paragraph (a)(2)(iii) of this section is used, the name of the food is "Cut ____", the blank being filled in with the name "Oysters" or "Cove oysters", if of the species *Ostrea virginica;* "Oysters" or "Pacific oysters", if of the species *Ostrea gigas;* "Oysters" or "Olympia oysters", if of the species *Ostrea lurida.*

(iv) In case a mixture of two or all such forms of oysters is used, the name is a combination of the names specified in this paragraph (a)(3) of the forms of oysters used, arranged in order of their predominance by weight.

(b) [Reserved]

(c) *Fill of container*—(1) The standard of fill of container for canned oysters is a fill such that the drained weight of oysters taken from each container is not less than 59 percent of the water capacity of the container.

(2) Water capacity of containers is determined by the general method provided in § 130.12(a) of this chapter.

(3) Drained weight is determined by the following method: Keep the unopened canned oyster container at a temperature of not less than 68° or more than 95° Fahrenheit for at least 12 hours immediately preceding the determination. After opening, tilt the container so as to distribute its contents evenly over the meshes of a circular sieve which has been previously weighed. The diameter of the sieve is 8 inches if the quantity of the contents of the container is less than 3 pounds, and 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is woven-wire cloth which complies with the specifications for such cloth set forth under "2380

Micron (No. 8)," in Table I of "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the United States Department of Commerce, National Bureau of Standards. Without shifting the material on the sieve, so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and the drained oysters. The weight so found, less the weight of the sieve, shall be considered to be the drained weight of the oysters.

(4) If canned oysters fall below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter in the manner and form therein specified, followed by the statement, "A can of this size should contain _____ oz. of oysters. This can contains only _____ oz", the blanks being filled in with the applicable figures.

§ 161.170 Canned Pacific salmon.

(a) *Identity*—(1) Canned Pacific salmon is the food prepared from one of the species of fish enumerated in paragraph (a)(2) of this section, prepared in one of the forms of pack specified in paragraph (a)(3) of this section, and to which may be added one or more of the optional ingredients specified in paragraph (a)(4) of this section. The food is packed in hermetically sealed containers and so processed by heat as to prevent spoilage and soften bones. The food is labeled in accordance with paragraph (a)(5) of this section.

(2)(i) The species of fish which may be used in this food are:

Oncorhynchus tshawytscha.	Chinook, king, spring.
Oncorhynchus nerka	Blueback, red, sockeye.
Oncorhynchus kisutch	Coho, Cohoe, medium red, silver.
Oncorhynchus gorbuscha.	Pink.
Oncorhynchus keta	Chum, keta.
Oncorhynchus masou	Masou, cherry.

(ii) For the purpose of paragraph (a)(5)(i) of this section, the common or usual name or names of each species of fish enumerated in paragraph (a)(2)(i) of this section is (are) the name(s) immediately following the scientific name of each species.

(3) The optional forms of canned Pacific salmon are processed from fish prepared by removing the head, gills, and tail, and the viscera, blood, fins, and damaged or discolored flesh to the greatest extent practicable in accordance with good manufacturing practice; and then washing. Canned Pacific salmon is prepared in one of the following forms of pack:

(i) "Regular" consists of sections or steaks which are cut transversely from the fish and filled vertically into the can. In preparation, segments of skin or large backbone may be removed. The sections or steaks are so packed that the cut surfaces approximately parallel the ends of the container. A small portion of salmon may be added if necessary to complete the fill of the container.

(ii) "Skinless and backbone removed" consists of the regular form of canned salmon set forth in paragraph (a)(3)(i) of this section from which the skin and vertebrae have been removed in accordance with good manufacturing practices.

(iii) "Minced salmon" consists of salmon which has been minced or ground.

(iv) "Salmon tips or tidbits" consists of small pieces of salmon.

(v) "No salt added" consists of canned salmon to which no salt has been added.

(4) One or more of the following optional ingredients may be added to the food:

(i) Salt.

(ii) Edible salmon oil comparable in color, viscosity, and flavor to the oil which would occur naturally in the species of salmon canned.

(5)(i) The name of the food is "salmon" together with the common or usual name or names of the species. At least one species name shall be printed in letters of the same style of type and not less in height than those used for the word "salmon".

(ii) (*a*) Whenever the form of pack is that described in paragrpah (a)(3)(ii), (iii), or (iv) of this section, the word or words describing the form of pack shall immediately precede or follow the name of the food without intervening written, printed, or graphic matter in the manner prescribed in § 101.3(c) of this chapter; for example, "red salmon" as the name of the food followed by "skinless and backbone removed".

(*b*) Whenver the form of pack is that described in paragraph (a)(3)(v) of this section and words describing the form of pack are declared on the label, the label shall also bear the statements required by § 105.69 of this chapter.

(iii) The name of each of the ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(b) [Reserved]

(c) *Fill of container*—(1) The standard of fill of container for canned salmon is a fill including all the contents of the container and is not less than the minimum net weight specified for the corresponding can size in the following table:

I. *Can size*	II. *Minimum net weight*
603x405	1.814 kg (64 oz).
301x411	454 g (16 oz).
301x408	439 g (15½ oz).
401x211	439 g (15½ oz).
607x406x108	439 g (15½ oz).
301x308	340 g (12 oz).
307x200.25	220 g (7¾ oz).
513x307x103	220 g (7¾ oz).
307x113	191 g (6¾ oz).
301x106	106 g (3¾ oz).
407x213x015	106 g (3¾ oz).

If the can size in question is not listed, calculate the value for Column II as follows: From the list, select as the comparable can size, that one having the nearest water capacity of the can size in question, multiply the net weight listed in Column II by the water capacity of the can size in question, and divide by the water capacity of the comparable can size. Water capacities are determined by the general method provided in § 130.12(a) of this chapter.

(2) Sampling and acceptance procedure: The sample size of the sample representing the lot will be selected in accordance with the sampling plan shown in paragraph (c)(2)(ii) of this section. A lot is to be considered acceptable when the average net weight of all the sample units is not less than the minimum net weight stated in paragraph (c)(1) of this section for the corresponding can size.

(i) Definitions of terms to be used in the sampling plans in paragraph (c)(2)(ii) of this section are as follows:

(*a*) *Lot.* A collection of primary containers or units of the same size, type, and style manufactured or packed under similar conditions and handled as a single unit of trade.

(*b*) *Lot size.* The number of primary containers or units in the lot.

(*c*) *Sample size* (*n*). The total number of sample units drawn for examination from a lot.

(*d*) *Sample unit.* A container, the entire contents of a container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for examination or testing as a single unit.

(ii) Sampling plans:

Lot size (primary containers):	*Size of container*[1] (*n*)
4,800 or less	13
4,801 to 24,000	21
24,001 to 48,000	29
48,001 to 84,000	48
84,001 to 144,000	84
144,001 to 240,000	126
Over 240,000	200

[1] Net weight equal to or less than 1 kg. (2.2 lb).

Lot size (primary containers):	*Size of container*[1] (*n*)
2,400 or less	13
2,401 to 15,000	21
15,001 to 24,000	29
24,001 to 42,000	48
42,001 to 72,000	84
72,001 to 120,000	126
Over 120,000	200

n-number of primary containers in sample.

[1] Net weight greater than 1 kg (2.2 lb) but not more than 4.5 kgs (10 lb).

(3) If canned salmon falls below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

§ 161.173 Canned wet pack shrimp and canned dry pack shrimp in nontransparent containers.

(a)-(b) [Reserved]

(c) *Fill of container*—(1) The standard of fill of nontransparent containers for canned wet pack shrimp is a fill such that the cut-out weight of shrimp taken from each can is not less than 64 percent of the water capacity of the container, and, for canned dry pack shrimp (except that packed in the nontransparent cylindrical container which is $2^{11}/_{16}$ inches in

diameter and 4 inches in height), is a fill such that the cut-out weight of shrimp taken from each can is not less than 60 percent of the water capacity of the container. The standard or fill for canned dry pack shrimp packed in the nontransparent cylindrical container which is $2^{11}/_{16}$ inches in diameter and 4 inches in height is a cut-out weight of not less than 6½ avoirdupois ounces of shrimp for each container. Water capacity of containers is determined by the general method provided in § 130.12(a) of this chapter. Cut-out weight is determined by the following method: Keep the unopened canned shrimp container at a temperature of not less than 68° nor more than 95° F for at least 12 hours immediately preceding the determination. After opening, tilt the container so as to distribute the shrimp evenly over the meshes of a circular sieve which has been previously weighed. The diameter of the sieve is 8 inches if the quantity of the contents of the container is less than 3 pounds, and 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is woven-wire cloth which complies with the specifications for such cloth set forth under "2380 Micron (No. 8)" in Table I of "Standard Specifications for Sieves," published March 1, 1940, in L.C. 584 of the United States Department of Commerce, National Bureau of Standards. Without shifting the material on the sieve, so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and the drained shrimp. The weight so found, less the weight of the sieve, shall be considered to be the cut-out weight of the shrimp.

(2) If canned wet pack shrimp or canned dry pack shrimp, in nontransparent containers, falls below the applicable standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill provided in § 130.14(b) of this chapter, in the manner and form therein specified.

§ 161.175 Frozen raw breaded shrimp.

(a) Frozen raw breaded shrimp is the food prepared by coating one of the optional forms of shrimp specified in paragraph (c) of this section with safe and suitable batter and breading ingredients as provided in paragraph (d) of this section. The food is frozen.

(b) The food tests not less than 50 percent of shrimp material as determined by the method prescribed in paragraph (g) of this section, except that if the shrimp are composite units the method prescribed in paragraph (h) of this section is used.

(c) The term "shrimp" means the tail portion of properly prepared shrimp of commercial species. Except for composite units, each shrimp unit is individually coated. The optional forms of shrimp are:

(1) Fantail or butterfly: Prepared by splitting the shrimp; the shrimp are peeled, except that tail fins remain attached and the shell segment immediately adjacent to the tail fins may be left attached.

(2) Butterfly, tail off: Prepared by splitting the shrimp; tail fins and all shell segments are removed.

(3) Round: Round shrimp, not split; the shrimp are peeled, except that tail fins remain attached and the shell segment immediately adjacent to the tail fins may be left attached.

(4) Round, tail off: Round shrimp, not split; tail fins and all shell segments are removed.

(5) Pieces: Each unit consists of a piece or a part of a shrimp; tail fins and all shell segments are removed.

(6) Composite units: Each unit consists of two or more whole shrimp or pieces of shrimp, or both, formed and pressed into composite units prior to coating; tail fins and all shell segments are removed; large composite units, prior to coating, may be cut into smaller units.

(d) The batter and breading ingredients referred to in paragraph (a) of this section are the fluid constituents and the solid constituents of the coating around the shrimp. These ingredients consist of suitable substances which are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act. Batter and breading ingredients that perform a useful function are regarded as suitable, except that artificial flavorings, artificial sweeteners, artificial colors, and chemical preservatives, other than those provided for in this paragraph, are not suitable ingredients of frozen raw breaded shrimp. Chemical preservatives that are suitable are:

(1) Ascorbic acid, which may be used in a quantity sufficient to retard development of dark spots on the shrimp; and

(2) The antioxidant preservatives listed in Subpart D of Part 182 of this chapter that may be used to retard development of rancidity of the fat content of the food, in amounts within the limits prescribed by that section.

(e) The label shall name the food, as prepared from each of the optional forms of shrimp specified in paragraph (c) (1) to (6), inclusive, of this section, and following the numbered sequence of such subparagraph, as follows:

(1) "Breaded fantail shrimp." The word "butterfly" may be used in lieu of "fantail" in the name.

(2) "Breaded butterfly shrimp, tail off."

(3) "Breaded round shrimp."

(4) "Breaded round shrimp, tail off."

(5) "Breaded shrimp pieces."

(6) Composite units:

(i) If the composite units are in a shape similar to that of breaded fish sticks the name is "Breaded shrimp sticks"; if they are in the shape of meat cutlets, the name is "Breaded shrimp cutlets".

(ii) If prepared in a shape other than that of sticks or cutlets, the name is "Breaded shrimp ————", the blank to be filled in with the word or phrase that accurately describes the shape, but which is not misleading.

In the case of the names specified in paragraphs (e) (1) through (5) of this section, the words in each name may be arranged in any order, provided they are so arranged as to be accurately descriptive of the food. The word "prawns" may be added in parentheses immediately after the word "shrimp" in the name of the food if the shrimp are of large size; for example, "Fantail breaded shrimp (prawns)". If the shrimp are from a single geographical area, the adjectival designation of that area may appear as part of the name; for example, "Breaded Alaskan shrimp sticks".

(f) The names of the optional ingredients used, as provided for in paragraph (d) of this section, shall be listed on the principal display panel or panels of the label with such prominence and conspicuousness as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase. If a spice that also imparts color is used, it shall be designated as "spice and coloring", unless the spice is designated by its specific name. If ascorbic acid is used to retard development of dark spots on the shrimp, it shall be designated as "Ascorbic acid added as a preservative" or "Ascorbic acid added to retard discoloration of shrimp". If any other antioxidant preservative, as provided in paragraph (d) of this section, is used, such preservative shall be designated by its common name followed by the statement "Added as a preservative".

(g) The method for determining percentage of shrimp material for those forms specified in paragraph (c) (1) through (5) of this section is as follows:

(1) *Equipment needed.* (i) Two-gallon container, approximately 9 inches in diameter.

(ii) Two-vaned wooden paddle, each vane measuring approximately 1¾ inches by 3¾ inches.

(iii) Stirring device capable of rotating the wooden paddle at 120 r.p.m.

(iv) Balance accurate to 0.01 ounce (or 0.1 gram).

(v) U.S. Standard sieve No. 20, 12-inch diameter.[*]

(vi) U.S. Standard sieve, ½-inch sieve opening, 12-inch diameter.

(vii) Forceps, blunt points.

(viii) Shallow baking pans.

(ix) Rubber-tipped glass stirring rod.

(2) *Procedure.* (i) Weigh the sample to be debreaded. Fill the container three-fourths full of water at 70°–80° F. Suspend the paddle in the container, leaving a clearance of at least 5 inches below the paddle vanes, and adjust speed to 120 r.p.m. Add shrimp and stir for 10 minutes. Stack the sieves, the ½-inch mesh over the No. 20, and pour the contents of the container onto them. Set the sieves under a faucet, preferably with spray at-

[*] The sieves shall comply with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L.C. 584 of the U.S. Department of Commerce, National Bureau of Standards.

tached, and rinse shrimp with no rubbing of flesh, being careful to keep all rinsings over the sieves and not having the stream of water hit the shrimp on the sieve directly. Lay the shrimp out singly on the sieve as rinsed. Inspect each shrimp and use the rubber-tipped rod and the spray to remove the breading material that may remain on any of them, being careful to avoid undue pressure or rubbing, and return each shrimp to the sieve. Remove the top sieve and drain on a slope for 2 minutes, then remove the shrimp to weighing pan. Rinse contents of the No. 20 sieve onto a flat pan and collect any particles other than breading (i.e., flesh and tail fins) and add to shrimp on balance pan and weigh.

(ii) Calculate percent shrimp material:

$$\text{Percent shrimp material} = \frac{\text{Weight of debreaded sample}}{\text{Weight of sample}} \times 100 + 2$$

(h) The method for determining percentage of shrimp material for composite units, specified in paragraph (c) (6) of this section, is as follows:

(1) *Equipment needed.* (i) Water bath (for example a 3-liter to 4-liter beaker).

(ii) Balance accurate to 0.1 gram.

(iii) Clip tongs of wire, plastic, or glass.

(iv) Stop-watch or regular watch readable to a second.

(v) Paper towels.

(vi) Spatula, 4-inch blade with rounded tip.

(vii) Nut picker.

(viii) Thermometer (immersion type) accurate to ±2° F.

(ix) Copper sulfate crystals ($CuSo_4 \cdot 5H_2O$).

(2) *Procedure.* (i) Weigh all composite units in the sample while they are still hard frozen.

(ii) Place each composite unit individually in a water bath that is maintained at 63° F–86° F, and allow to remain until the breading becomes soft and can easily be removed from the still frozen shrimp material (between 10 seconds to 80 seconds for composite units held in storage at 0° F). If the composite units were prepared using batters that are difficult to remove after one dipping, redip them for up to 5 seconds after the initial debreading and remove residual batter materials.

[NOTE.—Several preliminary trials may be necessary to determine the exact dip time required for "debreading" the composite units in a sample. For these trials only, a saturated solution of copper sulfate (1 pound of copper sulfate in 2 liters of tap water) is necessary. The correct dip time is the minimum time of immersion in the copper sulfate solution required before the breading can easily be scraped off: *Provided*, That the "debreaded" units are still solidly frozen and only a slight trace of blue color is visible on the surface of the "debreaded" shrimp material.]

(iii) Remove the unit from the bath; blot lightly with double thickness of paper toweling; and scrape off or pick out coating from the shrimp material with the spatula or nut picker.

(iv) Weigh all the "debreaded" shrimp material.

(v) Calculate the percentage of shrimp material in the sample, using the following formula:

$$\text{Percent shrimp material} = \frac{\text{Weight of debreaded shrimp sample}}{\text{Weight of sample}} \times 100$$

§ 161.176 Frozen raw lightly breaded shrimp.

Frozen raw lightly breaded shrimp complies with the provisions of § 161.175, except that it contains not less than 65 percent of shrimp material, as determined by the method prescribed in § 161.175 (g) or (h), as appropriate, and that in the name prescribed the word "lightly" immediately precedes the words "breaded shrimp".

§ 161.190 Canned tuna.

(a) *Identity*—(1) Canned tuna is the food consisting of processed flesh of fish of the species enumerated in paragraph (a) (2) of this section, prepared in one of the optional forms of pack specified in paragraph (a) (3) of this section, conforming to one of the color designations specified in paragraph (a) (4) of this section, in one of the optional packing media specified in paragraph (a) (5) of this section, and may contain one or more of the seasonings and flavorings specified in paragraph (a) (6) of this section. For the purpose of inhibiting the development of struvite crystals, sodium acid pyrophosphate may be added in a quantity not in excess of 0.5 percent by weight of the finished food. It is packed in hermetically sealed containers and so processed by heat as to prevent spoilage. It is labeled in accordance with the provisions of paragraph (a) (8) of this section.

(2) The fish included in the class known as tuna fish are:

Thunnus thynnus	Bluefin tuna.[9]
Thunnus maccoyii	Southern bluefin tuna.[9]
Thunnus orientalis	Oriental tuna.[11]
Thunnus germo	Albacore.[11]
Thunnus atlanticus	Blackfin tuna.[12]
Parathunnus mebachi	Big-eyed tuna.[11]
Neothunnus macropterus.	Yellowfin tuna.[11]
Neothunnus rarus	Northern bluefin tuna.[9]
Katsuwonus pelamis	Skipjack.[9]
Euthynnus alletteratus	Little tunny.[10]
Euthynnus lineatus	Little tunny.[10]
Euthynnus yaito	Kawakawa.[13]

[9] "A Comparison of the Bluefin Tunas, Genus Thunnus, from New England, Australia, and California," by H. C. Godsil and Edwin K. Holmberg, State of California, Department of Natural Resources Division of Fish and Game, Bureau of Marine Fisheries, Fish Bulletin No. 77 (1950).

[10] "Contributions to the Comparative Study of the So-called Scombroid Fishes," by Kamakichi Kishinouye, Journal of the College of Agriculture, Imperial University of Tokyo, Vol. VIII, No. 3 (1923).

[11] "A Systematic Study of the Pacific Tunas," by H. C. Godsil and Robert D. Byers, State of California, Department of Natural Resources, Division of Fish and Game, Bureau of Marine Fisheries, Fish Bulletin No. 60 (1944).

[12] "Descriptive Study of Certain Tuna-Like Fishes," by H. C. Godsil, State of California, Department of Fish and Game, Fish Bulletin No. 97.

[13] "Comparative Anatomy and Systematics of the Tunas, Genus Thunnus," by Robert H. Gibbs, Jr., and Bruce B. Collette, Division of Fishes, U.S. National Museum and Bureau of Commercial Fisheries, Fish and Wildlife Service, U.S. Department of the Interior, Fishery Bulletin Vol. 66, No. 1 (1967), pp. 65–130.

The description of each species will be found in the text to which reference is made.

(3) The optional forms of processed tuna consist of loins and other striated muscular tissue of the fish. The loin is the longitudinal quarter of the great lateral muscle freed from skin, scales, visible blood clots, bones, gills, viscera and from the nonstriated part of such muscle, which part (known anatomically as the median superficial muscle) is highly vascular in structure, dark in color because of retained blood, and granular in form. Canned tuna is prepared in one of the following forms of pack, the identity of which is determined in accordance with the methods prescribed in paragraph (c) (2) of this section.

(i) Solid or solid pack consists of loins freed from any surface tissue discolored by diffused hemolyzed blood, cut in transverse segments to which no free fragments are added. In containers of 1 pound or less of net contents, such segments are cut in lengths suitable for packing in one layer. In containers of more than 1 pound net contents, such segments may be cut in lengths suitable for packing in one or more layers of equal thickness. Segments are placed in the can with the planes of their transverse cut ends parallel to the ends of the can. A piece of a segment may be added if necessary to fill a container. The proportion of free flakes broken from loins in the canning operation shall not exceed 18 percent.

(ii) Chunk, chunks, chunk style consists of a mixture of pieces of tuna in which the original muscle structure is retained. The pieces may vary in size, but not less than 50 percent of the weight of the pressed contents of a container is retained on a ½-inch-mesh screen.

(iii) Flake or flakes consist of a mixture of pieces of tuna in which more than 50 percent of the weight of the pressed contents of the container will pass through a ½-inch-mesh screen, but in which the muscular structure of the flesh is retained.

(iv) Grated consists of a mixture of particles of tuna that have been reduced to uniform size, that will pass through a ½-inch-mesh screen, and in which the particles are discrete and do not comprise a paste.

(v) Any of the specified forms of pack of canned tuna may be smoked. Canned smoked tuna shall be labeled in accordance with the provisions of paragraph (a) (8) (v) of this section.

(4) Canned tuna, in any of the forms of pack specified in paragraph (a) (3) of this section, falls within one of the following color designations, measured by visual comparison with matte surface neutral reflectance standards corresponding to the specified Munsell units of value, determined in accordance with paragraph (a) (7) of this section.

(i) *White.* This color designation is limited to the species Thunnus germo (albacore), and is not darker than Munsell value 6.3.

(ii) *Light.* This color designation includes any tuna not darker than Munsell value 5.3.

(iii) *Dark.* This color designation includes all tuna darker than Munsell value 5.3.

(iv) *Blended.* This color designation may be applied only to tuna flakes specified in paragraph (a) (3) (iii) of this section, consisting of a mixture of tuna flakes of which not less than 20 percent by weight meet the color standard for either white tuna or light tuna, and the remainder of which fall within the color standard for dark tuna. The color designation for blended tuna is determined in accordance with paragraph (a) (7) of this section.

(5) Canned tuna is packed in one of the following optional packing media:

(i) Any edible vegetable oil other than olive oil, or any mixture of such oils not containing olive oil.

(ii) Olive oil.

(iii) Water.

(6) Canned tuna may be seasoned or flavored with one or more of the following:

(i) Salt.

(ii) Purified monosodium glutamate.

(iii) Hydrolyzed protein.

(iv) Hydrolyzed protein with reduced monosodium glutamate content.

(v) Spices or spice oils or spice extracts.

(vi) Vegetable broth in an amount not in excess of 5 percent of the volume capacity of the container, such broth to consist of a minimum of 0.5 percent by weight of vegetable extractives and to be prepared from two or more of the following vegetables: Beans, cabbage, carrots, celery, garlic, onions, parsley, peas, potatoes, green bell peppers, red bell peppers, spinach, and tomatoes.

(vii) Garlic.

(viii) Lemon flavoring to be prepared from lemon oil and citric acid together with safe and suitable carriers for the lemon oil which are present at nonfunctional and insignificant levels in the finished canned food. When lemon flavoring is added, a safe and suitable solubilizing and dispersing ingredient may be added in a quantity not exceeding 0.005 percent by weight of the finished food. A substance used in accordance with this paragraph is deemed to be suitable if it is used in an amount no greater than necessary to achieve the intended flavor effect, and is deemed to be safe if it is not a food additive as defined in section 201(s) of the act or, if it is a food additive as so defined, it is used in conformity with regulations established pursuant to section 409 of the act.

(7) For determination of the color designations specified in paragraph (a) (4) of this section, the following method shall be used: Recombine the separations of pressed cake resulting from the method prescribed in paragraph (c) (2) of this section. Pass the combined portions through a sieve fitted with woven-wire cloth of ¼-inch mesh which complies with the specifications for such wire cloth set forth in "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the U.S. Department of Commerce, National Bureau of Standards. Mix the sieved material and place a sufficient quantity into a 307 x 113 size container (bearing a top seam and having a false bottom approximately ½-inch deep and painted flat black inside and outside) so that after tamping and smoothing the surface of the sample the material will be ⅛-inch to ¼-inch below the top of the container. Within 10 minutes after sieving through the ¼-inch mesh woven-wire cloth, determine the Munsell value of sample surface.

(i) Determine the Munsell value of the sample surface so prepared. The following method may be used, employing an optical comparator, consisting of a lens and prism system which brings two beams of light, reflected from equal areas of sample surface and standard surface, respectively, together, within an eyepiece, so as to show an equally divided optical field. The scanned areas of sample and standard surface are not smaller than 2 square inches. Light reaching the eye is rendered sufficiently diffuse, by design of eyepiece and comparator, so that detail of the sample surface will remain undefined, to a degree such as to avoid visual confusion in observation of a match of over-all intensity of reflected light. The eyepiece contains a color filter centering at a wavelength between 550 mμ and 560 mμ. The filter does not pass appreciable visible radiation of wavelengths below 540 mμ or above 570 mμ. The passed wavelength band is of a monochromaticity sufficient to cause a sample and a neutral standard of equal reflectance to appear of the same hue. The comparator is rigidly mounted on a vertical stand attached to a base in which arrangement is provided for securely and accurately positioning two cans of size 307 x 113 in the two fields of view. Mounted on the base are two shaded lamps, which direct the center of their beams of light at about a 45° angle to the plane of the sample and standard surfaces. The lamps are so positioned that light from one bears mainly upon the sample surface and light from the other mainly on the standard surface, and are so placed in relation to sample and standard that no shadows, as from the can rims, appear in the fields of view. The lamps are strong enough to furnish adequate and convenient illumination through eyepiece and filter. Means is provided to alter the light intensity of one lamp in relation to the other, as may conveniently be achieved by using a 100-watt tungsten filament bulb in one lamp and using, in the other, a similar 150-watt bulb connected with the power source through a suitable rheostat. The stand is equipped with nonglossy black curtains on the side of the observer, to exclude variation in extraneous light reflected from the person of the observer.

(ii) To adjust the comparator, place a pair of matte surface standards of Munsell value 5.3, mounted as described in paragraph (a) (7) (iv) of this section, in position in the comparator base, and adjust the intensity of the variable lamp until the two halves of the optical field, viewed through the eyepiece, are of equal brightness. Then remove one of the standards and replace it with the prepared sample. Without altering any other adjustments, observe through the eyepiece whether the sample appears lighter or darker than the standard. In case of examination of albacore designated "white", conduct the procedure using standards of Munsell value 6.3.

(iii) The standards with which comparisons are made are essentially neutral matte-finish standards, equivalent in luminous reflectance of light of 555 mμ wavelength to 33.7 percent of the luminous reflectance of magnesium oxide (for Munsell value 6.3) and 22.6 percent of the luminous reflectance of magnesium oxide (for Munsell value 5.3), as given by the relationship between

Munsell value and luminous reflectance derived by a subcommittee of the Optical Society of America and published in the "Journal of the Optical Society of America," Volume 33, page 406 (1943).

(iv) These standards shall be cut in circles 3¼ inches in diameter and shall be mounted in 307 x 113 size containers, bearing a top seam and painted flat black inside and outside, so that the surfaces of the standards are 5/16 inch below the top of the containers in which they are mounted.

(v) In the case of blended tuna, the foregoing method shall be varied by first separating the tuna flakes of the two different colors before passing them through the ¼-inch mesh sieve, then proceeding with each portion separately for the determination of its color value, employing, if necessary, a sample container with false bottom greater than ½ inch deep.

(8) (i) The specified names of the canned tuna for which definitions and standards of identity are prescribed by this section, except where water is the packing medium or where the tuna is smoked, are formed by combining the designation of form of pack with the color designation of the tuna; for example, "Solid pack white tuna", "Grated dark tuna", etc. In the case of blended tuna, there shall be used both applicable color designations of the blended flakes, in precedence determined in accordance with the predominating portion found in the container; for example, "Blended white and dark tuna flakes", "Blended dark and light tuna flakes".

(ii) The specified name of canned tuna when water is used as the packing medium is formed as described in paragraph (a) (8) (i) of this section, followed by the words "in water"; for example, "Grated light tuna in water".

(iii) When the packing medium is vegetable oil or olive oil, the label shall bear the name of the optional packing medium used, as specified in paragraph (a) (5) of this section, preceded by the word "in" or the words "packed in". In case of the optional ingredient specified in paragraph (a) (5) (i) of this section, the name or names of the oil used may be stated, or the general term "vegetable oil" may be used.

(iv) In case solid pack tuna is packed in olive oil, the designation "Tonno" may also appear.

(v) In case any of the specified forms of canned tuna are smoked, the word "smoked" shall appear as a part of the name on the label; for example, "Smoked light tuna flakes".

(vi) Where the canned tuna contains one or more of the ingredients provided for in paragraph (a) (6) of this section, the label shall bear the statement "Seasoned with _____", the blank being filled in with the name or names of the ingredient or ingredients used, except that if the ingredient designated in paragraph (a) (6) (vi) of this section is used, the blanks shall be filled in with the term "vegetable broth"; and if the ingredient designated in paragraph (a) (6) (v) of this section is used alone, the label may alternatively bear either the statement "spiced" or the statement "with added spice"; and if salt is the only seasoning ingredient used, the label may alternatively bear any of the statements "salted", "with added salt", or "salt added". If the flavoring ingredients designated in paragraph (a) (6) (viii) of this section are used, the words "lemon flavored" or "with lemon flavoring" shall appear as a part of the name on the label; for example, "lemon flavored chunk light tuna". Citric acid and any optional solubilizing and dispersing agent used as specified in paragraph (a) (6) (viii) of this section in connection with lemon flavoring ingredients shall be designated on the label by its common or usual name.

(vii) Where the canned tuna contains the optional ingredient sodium acid pyrophosphate as provided in paragraph (a) (1) of this section, the label shall bear the statement "pyrophosphate added" or "with added pyrophosphate".

(viii) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the names of the optional ingredients used, as specified in paragraphs (a) (8) (iii), (vi), and (vii) of this section (except if lemon flavoring is added, this subparagraph applies only to the terms "lemon flavored" or "with lemon flavoring", not to the constituent ingredients of that flavoring or to any optional solubilizing or dispersing ingredient used in connection with lemon flavoring ingredients), shall immediately and conspicuously precede or follow such name without intervening, written, printed, or graphic matter, except that the common name of the species of tuna fish may so intervene; but the species name "albacore" may be employed only for canned tuna of that species which meets the color designation "white" as prescribed by paragraph (a) (4) (i) of this section.

(ix) Statements of optional ingredients present required by paragraph (a) (8) (vi) of this section, but not subject to the provisions of paragraph (a) (8) (viii) of this section shall be set forth on the label with such prominence and conspicuousness as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase.

(b) [Reserved]

(c) *Fill of container*—(1) The standard of fill of container for canned tuna is a fill such that the average weight of the pressed cake from 24 cans, as determined by the method prescribed by paragraph (c) (2) of this section, is not less than the minimum value specified for the corresponding can size and form of tuna ingredient in the following table:

I. Can size and form of tuna ingredient	II. Minimum value for weights of pressed cake (average of 24 cans)
211 x 109:	*Ounces*
Solid	2.25
Chunks	1.98
Flakes	1.98
Grated	2.00
307 x 113:	
Solid	4.47
Chunks	3.92
Flakes	3.92
Grated	3.96
401 x 206:	
Solid	8.76
Chunks	7.68
Flakes	7.68
Grated	7.76
603 x 408:	
Solid	43.2
Chunks	37.9
Flakes	37.9
Grated	38.3

If the can size in question is not listed, calculate the value for column II as follows: From the list select as the comparable can size that one having nearest the water capacity of the can size in question, multiply the value listed in column II for the same form of tuna ingredient by the water capacity of the can size in question, and divide by the water capacity of the comparable can size. Water capacities are determined by the general method provided in § 130.-12(a) of this chapter. For the purposes of this section, cans of dimensions 211 x 109 shall be deemed to have a water capacity at 68° F of 3.55 avoirdupois ounces of water; cans of dimensions 307 x 113, a water capacity of 7.05 avoirdupois ounces of water; cans of dimensions 401 x 206, a water capacity of 13.80 avoirdupois ounces of water; and cans of dimensions 603 x 408, a water capacity of 68.15 avoirdupois ounces of water.

(2) The methods referred to in paragraph (c) (1) of this section for determining the weight of the pressed cake and referred to in paragraph (a) (3) (i) of this section for determining the percent of free flakes and the percent of pieces that pass through a ½-inch-mesh sieve are as follows:

(i) Have each of the 24 cans and contents at a temperature of 75° F within ±5° F. Test each can in turn as follows:

(ii) Cut out the top of the can (code end), using a can opener that does not remove nor distort the double seam.

(iii) With the cut top held on the can contents, invert the can, and drain the free liquid by gentle finger pressure on the cut lid so that most of the free liquid drains from the can.

(iv) With the cut lid still in place, cut out the bottom of the can with the can opener, then turn the can upright and remove the cut can top (code end). Scrape off any adhering tuna particles into the tuna mass in the can.

(v) Place the proper size of press cylinder as provided in paragraph (c) (3) (i) of this section in a horizontal position on a table; then, using the cut bottom of the can as a pusher, gently force the can contents from the can into the cylinder so that the flat side of the can contents lies in contact with the bottom of the cylinder. Remove the bottom of the can that was used as the pusher and scrape any adhering particles from the can body and bottom of the can, and put them in the cylinder.

(vi) Place the cylinder plunger on top of the can contents in the cylinder. Remove the eyebolt and put the cylinder

and plunger in position on the press (paragraph (c)(3)(iii) of this section).

(vii) Begin the operation of the press and as soon as liquid is observed coming from the cylinder start timing the operation. Apply pressure to the plunger slowly and at a uniform rate, so that a full minute is used to reach a pressure of 384 pounds per square inch of plunger face in contact with the can contents. Hold this pressure for 1 additional minute and then release the pressure and disengage the plunger from the press shaft. Tip the press cylinder so that any free liquid is drained out.

(viii) Remove press cylinder with plunger from the press, insert eyebolt in plunger and withdraw it from the cylinder. Loosen the pressed cake from the cylinder with a thin blade and remove the entire pressed cake as gently as possible, to keep the mass in a single cake during this operation. Place the pressed cake and any pieces that adhered to the plunger and cylinder in a tared receiving pan and determine the weight of the pressed material.

(ix) For cans larger than 401 x 206, cut out the top of the can and drain off free liquid from the can contents as in operations described in paragraphs (c)(2)(ii) and (iii) of this section. Determine the gross weight of the can and remaining contents. Using a tared core cutter as provided for in paragraph (c)(3)(ii) of this section, cut vertically a core of the drained material in the can. Determine the weight of the core. With a thin spatula transfer the core to the pressing cylinder for 401 x 206 cans. Determine the weight of the pressed cake as in the operations described in paragraphs (c)(2)(v) through (viii) of this section. Remove the remaining drained contents of the can, reserving the contents for the determination of free flakes (paragraph (c)(2)(xi) of this section), weigh the empty can, and calculate the weight of the total drained material. Calculate the weight of pressed cake on the entire can basis by multiplying the weight of the pressed cake of the core by the ratio of the weight of the drained contents of the can to the weight of the core before pressing.

(x) Repeat the determination of weight of pressed cake on the remainder of the 24 cans and determine the average weight of pressed cake for the purpose of paragraph (c)(1) of this section.

(xi) Determination of free flakes: If the optional form of tuna ingredient is solid pack, determine the percent of free flakes. Any flakes resulting from the operations described in this paragraph (c)(2)(xi) or in other parts of this paragraph are to be weighed as free flakes. Only fragments that were broken in the canning procedure are considered to be free flakes. If the can is of such size that its entire drained contents were pressed as described in paragraphs (c)(2)(i) to (viii) of this section, inclusive, examine the pressed cake carefully for free flakes. Using a spatula, scrape free flakes gently from the outside of the cake. Weigh the aggregate free flakes that were broken from the loin segments in the canning procedure and calculate their percentage of the total weight of pressed cake. If the can is of such size that a core was cut for pressing as described in paragraph (c)(2)(ix) of this section, make the examination for free flakes on a weighed portion of the drained material remaining after the core was removed. The weight of the portion examined should approximately equal the weight of the core before pressing. Calculate the weight of the free flakes that were broken from the loins in the canning procedure as a percentage of the weight of the portion examined.

(xii) Determination of particle size: If the optional form of tuna ingredient is chunks, flakes, or grated, the pressed cake resulting from the operations described in paragraphs (c)(2)(i) to (ix) of this section, inclusive, is gently separated by hand, care being taken to avoid breaking the pieces. The separated pieces are evenly distributed over the top sieve of the screen separation equipment described in paragraph (c)(3)(iv) of this section. Beginning with the top sieve, lift and drop each sieve by its open edge three times. Each time, the open edge of the sieve is lifted the full distance permitted by the device. Combine and weigh the material remaining on the three top sieves (1½-inch, 1-inch, ½-inch screens), and determine the combined percentage retention by weight in relation to the total weight of the pressed cake.

(3)(i) The press cylinder and plunger referred to in paragraph (c)(2) of this section are made of stainless steel. The press cylinders are made with a lip to facilitate drainage of the liquid. Plungers have a threaded center hole, about half as deep as the thickness of the plunger, for receiving a ringbolt to assist in removing the plunger from the press cylinder. Dimensions for press cylinders and plungers are as follows:

For can size 211 x 109

Press cylinder:
Inside depth, approximately 3¾ inches.
Inside diameter, 2.593 inches.
Wall thickness, approximately ⅜ inch.
Plunger:
Thickness, approximately 1 inch.
Diameter, 2.568 inches.

For can size 307 x 113

Press cylinder:
Inside depth, approximately 4 inches.
Inside diameter, 3.344 inches.
Wall thickness, approximately 5/16 inch.
Plunger:
Thickness, approximately 1¼ inches.
Diameter, 3.319 inches.

For can size 401 x 206

Press cylinder:
Inside depth, approximately 4⅛ inches.
Inside diameter, 3.969 inches.
Wall thickness, approximately ½ inch.
Plunger:
Thickness, approximately 1¼ inches.
Diameter, 3.944 inches.

For can sizes where the diameter is greater than 401, the core cutter described in paragraph (c)(3)(ii) of this section shall be used and the resulting core pressed in the press cylinder for can size 401 x 206. For can sizes differing from those specified in this paragraph (c)(3)(i), special press cylinders and plungers may be used. Special press cylinders have inside diameters 1/10-inch less than the outside diameters, at the double seam, for the can sizes for which the cylinders are used; plunger diameters are 0.025-inch less than the inside diameters of the press cylinders.

(ii) The core cutter referred to in paragraph (c)(2)(ix) and (xi) of this section and paragraph (c)(3)(i) of this section is made from a previously sealed 300 x 407 can. The cover, including the top seam, is cut out. The edge is smoothed and sharpened. A small hole to permit passage of air is made in the bottom.

(iii) The hydraulic press referred to in paragraph (c)(2)(vi) to (x) of this section, inclusive, is made by so mounting a hydraulic jack, in a strong frame, that it will press horizontally against the center of the plunger in the press cylinder used. The frame is so braced that it does not change shape when pressure is applied. The gauge on the hydraulic jack is so calibrated that it will indicate, for the plunger being used, when the plunger is pressing against the contents of the press cylinder with a pressure of 384 pounds per square inch of plunger face.

(iv) The sieving device referred to in paragraph (c)(2)(xii) of this section consists of three sieves, each approximately 1 foot square, loosely mounted, one above the other, in a metal frame. The mesh in the top sieve complies with the specifications for 1½-inch woven-wire cloth as set forth in "Standard Specifications for Sieves," as published March 1, 1940, in L. C. 584 of the U.S. Department of Commerce, National Bureau of Standards. The meshes in the sieves below comply with similar specifications for 1-inch and ½-inch woven-wire cloth as set forth in the same publication. The sides of each sieve are formed, in a raised rim, from ¾-inch x ⅛-inch metal strap. The frame has tracks made of ⅜-inch angle metal to support each sieve under each side. The tracks are so positioned as to permit each sieve a free vertical travel of 1¾ inches.

(4) If canned tuna falls below the applicable standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill provided in § 130.14(b) of this chapter, in the manner and form therein specified.

PART 163—CACAO PRODUCTS

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Cacao Products

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Sec.
163.145 Mixed dairy product chocolates.
163.150 Sweet cocoa and vegetable fat (other than cacao fat) coating.
163.153 Sweet chocolate and vegetable fat (other than cacao fat) coating.
163.155 Milk chocolate and vegetable fat (other than cacao fat) coating.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046 as amended, 1055–1056 as amended (21 U.S.C. 341, 371) unless otherwise noted.

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Cacao Products

§ 163.110 Cacao nibs.

(a) Cacao nibs, cocoa nibs, cracked cocoa is the food prepared by heating and cracking dried or cured and cleaned cacao beans and removing shell therefrom. Cacao nibs or the cacao beans from which they are prepared may be processed by heating with one or more of the following optional alkali ingredients, added as such or in aqueous solution: Bicarbonate, carbonate, or hydroxide of sodium, ammonium, or potassium; or carbonate or oxide of magnesium; but for each 100 parts by weight of cacao nibs used, as such or before shelling from the cacao beans, the total quantity of such alkalis used is not greater in neutralizing value (calculated from the respective combining weights of such alkalis used) than the neutralizing value of 3 parts by weight of anhydrous potassium carbonate. The cacao shell content of cacao nibs is not more than 1.75 percent by weight (calculated to an alkali-free basis if they or the cacao beans from which they were prepared have been processed with alkali), as determined by the method prescribed under "Shell in Cacao Nibs—Tentative" beginning on page 208 [Ed. note, 10th edition, 1965, p. 180, secs. 12.009–12.013] of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Ed., 1940.

(b) When cacao nibs or the cacao beans from which they are prepared are processed, in whole or in part, with any optional alkali ingredient specified in paragraph (a) of this section, the label shall bear the statement "Processed with alkali"; but in lieu of the word "alkali" in such statement the specific common name of the optional alkali ingredient may be used. Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, such statement shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter.

§ 163.111 Chocolate liquor.

(a) Chocolate liquor, chocolate, baking chocolate, bitter chocolate, cooking chocolate, chocolate coating, bitter chocolate coating is the solid or semiplastic food prepared by finely grinding cacao nibs. To such ground cacao nibs, cacao fat or a cocoa or both may be added in quantities needed to adjust the cacao fat content of the finished chocolate liquor. (For the purposes of this section the term "cocoa" means breakfast cocoa, cocoa, low-fat cocoa, or any mixture of two or more of these.) Chocolate liquor may be spiced, flavored, or otherwise seasoned with one or more of the following optional ingredients, other than any such ingredient or combination of ingredients specified in paragraph (a) (1), (2), or (3) of this section which imparts a flavor that imitates the flavor of chocolate, milk, or butter:

(1) Ground spice.

(2) Ground vanilla beans; any natural food flavoring oil, oleoresin, or extract.

(3) Vanillin, ethyl vanillin, or other artificial food flavoring.

(4) Butter, milk fat, dried malted cereal extract, ground coffee, ground nut meats.

(5) Salt.

Any optional ingredient used with the cacao beans or cacao nibs from which such chocolate liquor is prepared, or used with any cocoa added in preparing such chocolate liquor, shall be considered to be an optional ingredient used with such chocolate liquor. The optional alkali ingredients specified for use with cacao nibs in § 163.110(a) may be used as optional ingredients with chocolate liquor; but for each 100 parts by weight of cacao nibs used in preparing the chocolate liquor, the total quantity of such alkalis used is not greater in neutralizing value (calculated from the respective combining weights of such alkalis used) than 3 parts by weight of anhydrous potassium carbonate. The finished chocolate liquor contains not less than 50 percent and not more than 58 percent by weight of cacao fat. Unless the chocolate liquor is seasoned with butter, milk fat, or ground nut meats, the percentage of cacao fat is determined by the method prescribed under "Fat Method I—Official" beginning on page 202 [Ed. note, 10th edition, 1965, p. 184, sec. 12.022] of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Ed., 1940.

(b) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in this section, showing the optional ingredients used shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter:

(1) When the food is seasoned with an optional ingredient specified in paragraph (a)(1) of this section the label shall bear the statement "Spiced", "Spice added", "With added spice", "Spiced with ------", or "With added ------", the blank being filled in with the specific common name of the spice used.

(2) When the food is flavored with an optional ingredient specified in paragraph (a)(2) of this section, the label shall bear the statement "Flavored", "Flavoring added", "With added flavoring", or "Flavored with ------", "------ added", or "With added ------", the blank being filled in with the specific common name of the flavoring used.

(3) When the food is flavored with an optional ingredient specified in paragraph (a)(3) of this section, the label shall bear the statement "Artificially flavored", "Artificial flavoring added", "With artificial flavoring", "Artificially flavored with ----", or "With ----, an artificial flavoring", the blank being filled in with the specific common name of the artificial flavoring used.

(4) When the food is seasoned with an optional ingredient specified in paragraph (a)(4) of this section, the label shall bear the statement "Seasoned with ----", the blank being filled in with the specific common name of the substance used as seasoning.

(5) When any optional alkali ingredient specified in § 163.110 (a) is used, the label shall bear the statement "Processed with alkali"; but in lieu of the word "alkali" in such statement the specific common name of the optional alkali ingredient may be used.

Label statements prescribed in paragraph (b) (1) to (4), inclusive, of this section may be combined, as for example, "With added cinnamon, vanilla, and ethyl vanillin, an artificial flavoring".

§ 163.112 Breakfast cocoa.

(a) Breakfast cocoa, high fat cocoa is the food prepared by pulverizing the residual material remaining after part of the cacao fat has been removed from ground cacao nibs. It may be spiced, flavored, or otherwise seasoned with one or more of the following optional ingredients, other than any such ingredient or combination of ingredients which imparts a flavor that imitates the flavor of chocolate, milk, or butter:

(1) Ground spice.

(2) Ground vanilla beans; any natural food flavoring oil, oleoresin, or extract.

(3) Vanillin, ethyl vanillin, or other artificial food flavoring.

(4) Salt.

Any optional ingredient used with the cacao beans, cacao nibs, or ground cacao nibs from which such breakfast cocoa is prepared shall be considered to be an optional ingredient used with such breakfast cocoa. The optional alkali ingredients specified for use with cacao nibs in § 163.110(a) may be used as optional ingredients with breakfast cocoa; but for each 100 parts by weight of cacao nibs used in preparing the breakfast cocoa, the total quantity of such alkalis used is not greater in neutralizing value (calculated from the respective combining weights of such alkalis used) than 3 parts by weight of anhydrous potassium carbonate. The finished breakfast cocoa contains not less than 22 percent of cacao fat, as determined by the method prescribed under "Fat Method I—Official" beginning on page 202 [Ed. note, 10th edition, 1965, p. 184, sec. 12.022] of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Ed., 1940.

(b) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in this section, showing the optional ingredients used shall immediately and conspicuously precede or follow such

name, without intervening written, printed, or graphic matter:

(1) When the food is seasoned with an optional ingredient specified in paragraph (a)(1) of this section, the label shall bear the statement "Spiced", "Spice added", "With added spice", "Spiced with ____", or "With added ____", the blank being filled in with the specific common name of the spice used.

(2) When the food is flavored with an optional ingredient specified in paragraph (a)(2) of this section, the label shall bear the statement "Flavored", "Flavoring added", "With added flavoring", "Flavored with ____", "____ added", or "With added ____", the blank being filled in with the specific common name of the flavoring used.

(3) When the food is flavored with an optional ingredient specified in paragraph (a)(3) of this section, the label shall bear the statement "Artificially flavored", "Artificial flavoring added", "With artificial flavoring", "Artificially flavored with ____", or "With ____, an artificial flavoring", the blank being filled in with the specific common name of the artificial flavoring used.

(4) When any optional alkali ingredient specified in § 163.110(a) is used, the label shall bear the statement "Processed with alkali"; but in lieu of the word "alkali" in such statement the specific common name of the optional alkali ingredient may be used.

Label statements prescribed by paragraph (b) (1) to (4), inclusive, of this section may be combined, as for example, "With added cinnamon, vanilla, and ethyl vanillin, an artificial flavoring".

§ 163.113 Cocoa.

Cocoa, medium fat cocoa conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for breakfast cocoa by § 163.112, except that it contains less than 22 percent but not less than 10 percent of cacao fat, as determined by the method referred to in § 163.112(a).

§ 163.114 Low-fat cocoa.

Low-fat cocoa conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for breakfast cocoa by § 163.12, except that it contains less than 10 percent of cacao fat as determined by the method referred to in § 163.112(a).

§ 163.117 Cocoa with dioctyl sodium sulfosuccinate for manufacturing.

(a) Cocoa with dioctyl sodium sulfosuccinate for manufacturing is the food additive complying with the provisions § 172.520 of this chapter. It conforms to the definition and standard of identity and is subject to the requirements for label statement of optional ingredients prescribed for breakfast cocoa by § 163.112, or for cocoa by § 163.113, or low-fat cocoa by § 163.114, except that the food additive contains dioctyl sodium sulfosuccinate (complying with the requirements of § 172.810 of this chapter including the limit of not more than 0.4 percent by weight of the finished food additive).

(b) The name of the food additive is "cocoa with dioctyl sodium sulfosuccinate for manufacturing" to which is added any modifier of the word "cocoa" required by the definition and standard of identity to which the food additive otherwise conforms. When the food additive is used in a fabricated food, the words "for manufacturing" may be omitted from any declaration of ingredients required under § 101.4 of this chapter.

§ 163.123 Sweet chocolate.

(a) Sweet chocolate, sweet chocolate coating is the solid or semiplastic food the ingredients of which are intimately mixed and ground, prepared from chocolate liquor (with or without the addition of cacao fat) sweetened with one of the optional saccharine ingredients specified in paragraph (b) of this section. It may be spiced, flavored, or otherwise seasoned with one or more of the optional ingredients specified in paragraph (c) of this section, other than any such ingredient or combination of ingredients which imparts a flavor that imitates the flavor of chocolate, milk, or butter. One of the optional emulsifying ingredients or combinations of ingredients specified in paragraph (d) of this section may be used, subject to the conditions therein prescribed. One or more of the optional dairy ingredients specified in paragraph (e) of this section may be used in such quantity that the finished sweet chocolate contains less than 12 percent by weight of milk constituent solids. If chocolate liquor with any optional ingredient specified in § 163.111(a) is used, such ingredient shall be considered to be an optional ingredient used with the sweet chocolate. The finished sweet chocolate contains not less than 15 percent by weight of chocolate liquor, calculated by subtracting from the weight of chocolate liquor used the weight of cacao fat therein and the weights therein of alkali and seasoning ingredients, if any, multiplying the remainder by 2.2, dividing the result by the weight of the finished sweet chocolate, and multiplying the quotient by 100. Bittersweet chocolate is sweet chocolate which contains not less than 35 percent by weight of chocolate liquor, calculated in the same manner.

(b) The optional saccharine ingredients referred to in paragraph (a) of this section are:

(1) Sugar, or partly refined cane sugar, or both.

(2) Any mixture of dextrose and sugar or partly refined cane sugar or both in which the weight of the solids of the dextrose used is not more than one-third of the total weight of the solids of all the saccharine ingredients used.

(3) Any mixture of dried corn sirup or dried glucose sirup and sugar or partly refined cane sugar or both in which the weight of the solids of the dried corn sirup or dried glucose sirup used is not more than one-fourth of the total weight of the solids of all the saccharine ingredients used.

(4) Any mixture of dextrose and dried corn sirup or dried glucose sirup and sugar or partly refined cane sugar or both in which three times the weight of the solids of the dextrose used plus four times the weight of the solids of the dried corn sirup or of the solids of the dried glucose sirup used is not more than the total weight of the solids of all the saccharine ingredients used.

(c) The optional ingredients for spicing, flavoring, or otherwise seasoning referred to in paragraph (a) of this section are:

(1) Ground spice.

(2) Ground vanilla beans; any nautral food flavoring oil or oleoresin or extract.

(3) Ground coffee.

(4) Ground nut meats.

(5) Honey, molasses, brown sugar, maple sugar.

(6) Dried malted cereal extract.

(7) Salt.

(8) Vanillin, ethyl vanillin, or other artificial food flavoring.

(d) The optional emulsifying ingredient or combination of ingredients referred to in paragraph (a) of this section is:

(1) Lecithin, with or without related natural phosphatides, in an amount not to exceed 0.5 percent by weight of the finished food (with or without a vegetable food fat carrier in an amount not to exceed two-thirds of the weight of the emulsifying ingredient used); or

(2) Monoglycerides and diglycerides of fat-forming fatty acids in combination with monosodium phosphate derivatives thereof, in an amount not to exceed 0.5 percent of the weight of the finished food (with or without a vegetable food fat carrier in an amount not to exceed two-thirds of the weight of the emulsifying ingredient used); or

(3) Sorbitan monostearate, complying with the requirements of § 172.842 of this chapter, in an amount not to exceed 1 percent of the weight of the finished food; or

(4) Polysorbate 60, complying with the requirements of § 172.836 of this chapter, in an amount not to exceed 0.5 percent of the weight of the finished food; or

(5) Any combination of two or more of the foregoing each within the limits prescribed in paragraph (d) (1), (2), (3), and (4) of this section provided that the total quantity of any two or all three of the emulsifiers specified in paragraph (d) (2), (3), and (4) of this section does not exceed 1 percent by weight of the finished food and the total quantity of the emulsifiers specified in paragraph (d) (1) and (2) of this section does not exceed 0.5 percent of the weight of the finished food.

(e) The optional dairy ingredients referred to in paragraph (a) of this section are:

(1) Cream, milk fat, butter.

(2) Milk, concentrated milk, evaporated milk, sweetened condensed milk, dried milk.

(3) Skim milk, concentrated skim milk, evaporated skim milk, sweetened condensed skim milk, nonfat dry milk.

(4) Concentrated buttermilk, dried buttermilk.

(5) Malted milk.

(f) For the purpose of this section:

(1) The term "dextrose" means the anhydrous refined monosaccharide obtained from hydrolyzed starch.

(2) The term "dried corn sirup" means the product obtained by drying incompletely hydrolyzed cornstarch; its solids contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose.

(3) The term "dried glucose sirup" means the product obtained by drying "glucose sirup". "Glucose sirup" is a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of glucose sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose.

(g) "Semisweet chocolate", "bittersweet chocolate", "semisweet chocolate coating", and "bittersweet chocolate coating" are alternate names for sweet chocolate which contains not less than the minimum quantity of chocolate liquor prescribed for bittersweet chocolate by paragraph (a) of this section.

(h) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in this paragraph showing the optional ingredients used shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter:

(1) When the food is flavored with an optional ingredient specified in paragraph (c)(8) of this section, the label shall bear the statement "Artificially flavored", "Artificial flavoring added", "With artificial flavoring", "Artificially flavored with ----------", or "With ----------, an artificial flavoring", the blank being filled in with the specific common name of the artificial flavoring used.

(2) When an optional emulsifying ingredient or combination of ingredients specified in paragraph (d) of this section is used, the label shall bear the statement "Emulsifier added", "With added emulsifier", or "---------- added as (an) emulsifier(s)", the blank being filled in with the common name(s) of the emulsifier(s) used.

(3) When any optional alkali ingredient specified in § 163.110(a) is used, the label shall bear the statement "Processed with alkali", but in lieu of the word "alkali" in such statement the specific common name of the optional alkali ingredient may be used.

In cases where two or more of the statements set forth in this paragraph are required, such statements may be combined in a manner which is appropriate and not misleading.

§ 163.130 Milk chocolate.

(a) Milk chocolate, sweet milk chocolate, milk chocolate coating, sweet milk chocolate coating is the solid or semiplastic food the ingredients of which are intimately mixed and ground, prepared from chocolate liquor (with or without the addition of cacao fat) and one or more of the optional dairy ingredients specified in paragraph (b) of this section, sweetened with one of the optional saccharine ingredients specified in § 163.123 (b) and (f). It may be spiced, flavored, or otherwise seasoned with one or more of the optional ingredients specified in paragraph (c) of this section, other than any such ingredient or combination of ingredients which imparts a flavor that imitates the flavor of chocolate, milk, or butter. One of the optional emulsifying ingredients or combinations of ingredients specified in paragraph (d) of this section may be used, subject to the conditions therein prescribed. If chocolate liquor with any optional ingredient specified in § 163.111(a) is used, such ingredient shall be considered to be an optional ingredient used with the milk chocolate. The finished milk chocolate contains not less than 3.66 percent by weight of milk fat, not less than 12 percent by weight of milk solids, and not less than 10 percent by weight of chocolate liquor as calculated by subtracting from the weight of chocolate liquor used the weight of cacao fat therein and the weights therein of alkali and seasoning ingredients, if any, multiplying the remainder by 2.2, dividing the result by the weight of the finished milk chocolate, and multiplying the quotient by 100.

(b) The optional dairy ingredients referred to in paragraph (a) of this section are milk, concentrated milk, evaporated milk, sweetened condensed milk, dried milk, butter, milk fat, cream, skim milk, concentrated skim milk, evaporated skim milk, sweetened condensed skim milk, and nonfat dry milk; but in any such ingredient or combination of two or more of such ingredients used, the weight of nonfat milk solids is not more than 2.43 times and not less than 1.20 times the weight of milk fat therein.

(c) The optional ingredients for spicing, flavoring, or otherwise seasoning referred to in paragraph (a) of this section are:

(1) Ground spice.

(2) Ground vanilla beans; any natural food flavoring oil or oleoresin or extract.

(3) Ground coffee.

(4) Ground nut meats.

(5) Honey, molasses, brown sugar, maple sugar.

(6) Dried malted cereal extract.

(7) Salt.

(8) Vanillin, ethyl vanillin, or other artificial food flavoring.

(d) The optional emulsifying ingredient or combination of ingredients referred to in paragraph (a) of this section is:

(1) Lecithin, with or without related natural phosphatides, in an amount not to exceed 0.5 percent by weight of the finished food (with or without a vegetable food fat carrier in an amount not to exceed two-thirds of the weight of the emulsifying ingredient used); or

(2) Monoglycerides and diglycerides of fat-forming fatty acids in combination with monosodium phosphate derivatives thereof, in an amount not to exceed 0.5 percent of the weight of the finished food (with or without a vegetable food fat carrier in an amount not to exceed two-thirds of the weight of the emulsifying ingredient used); or

(3) Sorbitan monostearate, complying with the requirements of § 172.842 of this chapter, in an amount not to exceed 1 percent of the weight of the finished food; or

(4) Polysorbate 60, complying with the requirements of § 172.836 of this chapter, in an amount not to exceed 0.5 percent of the weight of the finished food; or

(5) Any combination of two or more of the foregoing each within the limits prescribed in paragraph (d) (1), (2), (3), and (4) of this section provided that the total quantity of any two or all three of the emulsifiers specified in paragraph (d) (2), (3), and (4) of this section does not exceed 1 percent by weight of the finished food and the total quantity of the emulsifiers specified in paragraph (d) (1) and (2) of this section does not exceed 0.5 percent of the weight of the finished food.

(e) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in this paragraph showing the optional ingredients used shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter:

(1) When the food is flavored with an optional ingredient specified in paragraph (c)(8) of this section, the label shall bear the statement "Artificially flavored", "Artificial flavoring added", "With artificial flavoring", "Artificially flavored with ----------", or "With ----------, an artificial flavoring", the blank being filled in with the specific common name of the artificial flavoring used.

(2) When an optional emulsifying ingredient or combination of ingredients specified in paragraph (d) of this section is used, the label shall bear the statement "Emulsifier added", "With added emulsifier", or "---------- added as (an) emulsifier(s)", the blank being filled in with the common name(s) of the emulsifier(s) used.

(3) When any optional alkali ingredient specified in § 163.110(a) is used, the label shall bear the statement "Processed with alkali," but in lieu of the word "alkali" in such statement the specific common name of the optional alkali ingredient may be used.

In cases where two or more of the statements set forth in this paragraph are required, such statements may be combined in a manner which is appropriate and not misleading.

§ 163.135 Buttermilk chocolate.

Buttermilk chocolate, buttermilk chocolate coating conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed

for milk chocolate by § 163.130, except that:

(a) The dairy ingredients used are limited to sweet cream buttermilk, concentrated sweet cream buttermilk, dried sweet cream buttermilk, or any combination of two or all of these.

(b) The finished buttermilk chocolate contains less than 3.66 percent by weight of milk fat and, instead of milk solids, it contains not less than 12 percent by weight of sweet cream buttermilk solids.

§ 163.140 Skim milk chocolate.

Skim milk chocolate, sweet skim milk chocolate, skim milk chocolate coating, sweet skim milk chocolate coating conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for milk chocolate by § 163.130, except that:

(a) The dairy ingredients used are limited to skim milk, concentrated skim milk, evaporated skim milk, sweetened condensed skim milk, nonfat dry milk, and any combination of two or more of these.

(b) The finished skim milk chocolate contains less than 3.66 percent by weight of milk fat and, instead of milk solids, it contains not less than 12 percent by weight of skim milk solids.

§ 163.145 Mixed dairy product chocolates.

(a) The articles for which definitions and standards of identity are prescribed by this section are the foods each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for milk chocolate by § 163.130, except that:

(1) The dairy ingredient used in each such article is a mixture of two or more of the following four components:

(i) Any dairy ingredient or combination of such ingredients specified in § 163.130(b) which is within the limits of the ratios specified therein for nonfat milk solids to milk fat.

(ii) One or more of the five skim milk ingredients specified in § 163.140.

(iii) One or more of the three sweet cream buttermilk ingredients specified in § 163.135.

(iv) Malted milk.

(2) Each of the finished articles may contain less than 3.66 percent by weight of milk fat and, instead of milk solids, it contains not less than 12 percent by weight of milk constituent solids of the components used. The quantity of each component used in any such mixture is such that no component contributes less than one-third of the weight of milk constituent solids contributed by that component used in largest proportion. When any such mixture is of components (i) and (ii) of paragraph (a)(1) of this section, the quantity of nonfat milk solids in such mixture is more than 2.43 times the quantity of milk fat therein. For the purposes of paragraph (b) of this section, the designation of each of the components listed above is respectively "Milk", "Skim milk", "Buttermilk", and "Malted milk".

(b) The name of each such article is "Chocolate" or "Chocolate coating" preceded by the designations prescribed by paragraph (a) of this section for each component of the dairy ingredients used, such designations appearing in the order of predominance, if any, of the weight of milk constituent solids in each such component, (e.g., "Milk and skim milk chocolate").

§ 163.150 Sweet cocoa and vegetable fat (other than cacao fat) coating.

Sweet cocoa and vegetable fat (other than cacao fat) coating conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for sweet chocolate by § 163.123, except that:

(a) In its preparation cocoa is used, instead of chocolate liquor, in such quantity that the finished food contains not less than 6.8 percent by weight of the nonfat cacao portion of such cocoa, calculated by subtracting from the weight of cocoa used the weight of cacao fat therein and the weight therein of alkali and seasoning ingredients, if any, dividing the remainder by the weight of the finished food, and multiplying the quotient by 100. (For the purposes of this section, the term "cocoa" means breakfast cocoa, cocoa, low-fat cocoa, or any mixture of two or more of these.)

(b) In its preparation is added one or any combination of two or more vegetable food oils, vegetable food fats, or vegetable food stearins, other than cacao fat, which oil, fat, stearin, or combination has a melting point higher than that of cacao fat. Any such oil or fat may be hydrogenated.

(c) The requirement of § 163.123(a) that the milk constituent solids be less than 12 percent by weight does not apply.

§ 163.153 Sweet chocolate and vegetable fat (other than cacao fat) coating.

(a) Sweet chocolate and vegetable fat (other than cacao fat) coating conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for sweet chocolate by § 163.123, except that:

(1) In its preparation there is added one or any combination of two or more vegetable food oils or vegetable food fats, other than cacao fat, which oil, fat, or combination may be hydrogenated and which has a melting point lower than that of cacao fat.

(2) Of the emulsifying ingredients and combinations of ingredients listed in § 163.123(d), only the ingredients specified in § 163.123(d) (1) and (2), alone or in combination, may be used subject to the limitation that the total quantity of these ingredients does not exceed 0.5 percent by weight of the finished food.

(b) The provisions of this section shall not be construed as applicable to any article by reason of the addition thereto of a vegetable food fat other than cacao fat as a carrier of emulsifying ingredients, as authorized and within the limits prescribed by § 163.123(d) (1) and (2).

§ 163.155 Milk chocolate and vegetable fat (other than cacao fat) coating.

(a) Milk chocolate and vegetable fat (other than cacao fat) coating, sweet milk chocolate and vegetable fat (other than cacao fat) coating conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for milk chocolate by § 163.130, except that:

(1) In its preparation there is added one or any combination of two or more vegetable food oils or vegetable food fats, other than cacao fat, which oil, fat, or combination may be hydrogenated and which has a melting point lower than that of cacao fat.

(2) Of the emulsifying ingredients and combinations of ingredients listed in § 163.130(d), only the ingredients specified in § 163.130(d) (1) and (2), alone or in combination, may be used subject to the limitation that the total quantity of these ingredients does not exceed 0.5 percent by weight of the finished food.

(b) The provisions of this section shall not be construed as applicable to any article by reason of the addition thereto of a vegetable food fat other than cacao fat as a carrier of emulsifying ingredients, as authorized and within the limits prescribed by § 163.130(d) (1) and (2).

PART 164—TREE NUT AND PEANUT PRODUCTS

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Tree Nut and Peanut Products

Sec.
164.110 Mixed nuts.
164.120 Shelled nuts in rigid or semirigid containers.
164.150 Peanut butter.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046 as amended, 1055–1056 as amended by 70 Stat. 919, 72 Stat. 948 (21 U.S.C. 341, 371).

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Tree Nut and Peanut Products

§ 164.110 Mixed nuts.

(a) Mixed nuts is the food consisting of a mixture of four or more of the optional shelled tree nut ingredients, with or without one or more of the optional shelled peanut ingredients, of the kinds prescribed by paragraph (b) of this section; except that when 2 ounces or less of the food is packed in transparent containers, three or more of the optional tree nut ingredients shall be present. Each such kind of nut ingredient when used shall be present in a quantity not less than 2 percent and not more than 80 percent by weight of the finished food. For purposes of this section, each kind of tree nut and peanut is an optional ingredient that may be prepared by any suitable method in accordance with good manufacturing practice. The finished food may contain one or more of the optional nonnut ingredients provided for in paragraph (c) of this section.

(b) The optional shelled nut ingredients referred to in paragraph (a) of this section are:

(1) Almonds, black walnuts, Brazil nuts, cashews, English walnuts (alternatively "walnuts"), filberts, pecans, and other suitable kinds of tree nuts.

(2) Peanuts of the Spanish, Valencia, Virginia, or similar varieties, or any combination of two or more such varieties.

(c) The optional nonnut ingredients referred to in paragraph (a) of this section consist of suitable substances that are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act. Nonnut ingredients that perform a useful function are regarded as suitable, except that color additives are not suitable ingredients of the food.

(d) The name of the food is "mixed nuts". If the percentage of a single tree nut ingredient or the total peanut content by weight of the finished food exceeds 50 percent but not 60 percent, the statement "contains up to 60% ------" or "contains 60% ------" or "60% ------" shall immediately follow the name "mixed nuts" and shall appear on the same background, be of the same color or, in the case of multicolors, in the color showing distinct contrast with the background, and be in letters not less than one-half the height of the largest letter in the words "mixed nuts". The blank is to be filled in with the appropriate name of the predominant nut ingredient; for example, "contains up to 60% pecans" or "contains up to 60% Spanish peanuts". The numbers "70" or "80" shall be substituted for the number "60" when the percentage of the predominant nut ingredient exceeds 60 but not 70, or exceeds 70 but not 80, respectively. Compliance with the requirements for percentage of nut ingredients of this section and the fill of container requirements of § 164.120(c) will be determined by the following procedure:

(1) Take at random from a lot, in the case of containers bearing a weight declaration of 16 ounces or less, at least 24 containers, and for containers bearing a weight declaration of more than 16 ounces, enough containers to provide a total quantity of at least 24 pounds of nuts.

(2) If compliance with § 164.120(c) is to be determined, first follow the procedure set forth therein.

(3) Determine the percent by weight of each nut ingredient present in each container separately. Calculate the average percentage of each nut ingredient present. If the average percent found for each nut ingredient present is 2 percent or more and none of the individual nut ingredients exceeds 80 percent by weight of the finished food, the lot will be deemed to be in compliance with the percentage requirements of paragraph (a) of this section. If the average percent found for a single nut ingredient exceeds 50 percent by weight of the finished food and the average percent found is within the range indicated by the number declared on the label in accordance with this paragraph, the lot will be deemed to be in compliance with the labeling requirements of this paragraph.

(e) Optional nut ingredients and optional nonnut ingredients used in the food, as provided for in paragraphs (b) and (c) of this section, shall be declared on the label by their common names in the order of decreasing predominance by weight except that:

(1) If the Spanish variety of peanuts is used, it shall be declared as "Spanish peanuts". Other varieties of peanuts shall be declared as "peanuts", or alternatively "---------- peanuts", the blank being filled in with the varietal name of the peanuts used.

(2) If the peanut ingredient or ingredients as provided for in paragraph (b)(1) of this section are unblanched, the label shall show that fact by such statement as "Peanuts unblanched", "Peanuts skins on," or words of similar import, unless the vignette clearly depicts peanuts with skins on.

(3) Vegetable oils used shall be declared by the words "Vegetable oil" or "Hydrogenated vegetable oil", or alternatively "---------- oil", or "Hydrogenated ---------- oil", as the case may be, the blank being filled in with the name or names of the vegetable source(s) of the oil. For the purposes of this section, hydrogenated vegetable oil shall be considered to include partially hydrogenated vegetable oil.

(4) When antioxidant preservatives are used in the finished food, the label shall bear the statement "---------- added as a preservative" or "---------- added to inhibit rancidity", the blank being filled in with the name or names of the preservative(s) used.

(f) The words and statements specified in paragraph (e) of this section showing the optional ingredients present shall be listed on the principal display panel or panels or any appropriate information panel without obscuring design, vignettes, or crowding. The declaration shall appear in conspicuous and easily legible letters of boldface print or type the size of which shall be not less than one-half of that required by Part 101 of this chapter for the statement of net quantity of contents appearing on the label, but in no case less than one-sixteenth of an inch in height. The entire ingredient statement shall appear on at least one panel of the label. If the label bears any pictorial representation of the mixture of nuts, it shall depict the relative proportions of the nut ingredients of the food. If the label bears a pictorial representation of only one of each nut ingredient present, the nuts shall be depicted in the order of decreasing predominance by weight. A factual statement that the food does not contain a particular nut ingredient or ingredients may be shown on the label if the statement is not misleading and does not result in an insufficiency of label space for the proper declaration of information required by or under authority of the act to appear on the label.

§ 164.120 Shelled nuts in rigid or semirigid containers.

(a)–(b) [Reserved]

(c) *Fill of container*—(1) The standard of fill for shelled nuts in rigid or semirigid containers is a fill such that the average volume of nuts, from the number of containers specified in § 164.110(d)(1), is not less than 85 percent of the container volume as determined by the method in paragraph (c)(2) of this section.

(2) The method for determining the percent of fill is as follows:

(i) For the shelled nuts in each container, determine the loose volume, the settled volume, and the average volume in cubic centimeters. For the purposes of this subparagraph, consider volume in milliliters to be numerically equal to volume in cubic centimeters. Open the container and pour the nuts loosely into a vertical graduated cylinder (do not tilt) of appropriate size fitted with a funnel which has been modified, if necessary, to provide a minimum opening of 1½-inch diameter. (If the loose volume of the nuts is less than 500 milliliters, use a 500-milliliter cylinder with an inside diameter of approximately 1⅞ inches; but if the loose volume is 500 milliliters or more, use a 1,000-milliliter cylinder with an inside diameter of approximately 2¼ inches.) Without shaking the cylinder, estimate the location of a horizontal plane representing the average height of the product, read the volume of the nuts, and record as the loose volume. Raise the cylinder 2 inches and allow it a free vertical drop onto a level, firm, but resilient surface (do not tamp) for a total of 5 times and observe the volume as above. Repeat in successive five-drop increments until the nuts have so settled that the volume decreases less than 2 percent in the last five-drop increment. Read the last volume in the manner described above and record as the settled volume. The arithmetical average of the loose volume and the settled volume equals the average volume of nuts.

(ii) Classify the container by shape and determine its volume in cubic centimeters according to one of the following methods as appropriate:

(*a*) For containers of irregular shape, including glass jars, follow the general method for water capacity of containers as prescribed in § 130.12(a) of this chapter and determine the container volume, considering the water capacity in grams to be numerically equivalent to volume in cubic centimeters, or the water capacity in ounces (avoirdupois) to be equivalent to 28.35 cubic centimeters per ounce.

(*b*) For box-shaped containers (that is, with opposite sides parallel), measure the inside height, width, and depth and calculate the volume as the product of these three dimensions. For such containers used to enclose vacuum packs and containing 4 ounces or less of the

product, consider the height to be the inside height minus three-eighths inch.

(c) For cylindrical containers, calculate the container volume in cubic centimeters as the product of the height times the square of the diameter, both measured in inches, times 12.87; or as the product of the height times the square of the diameter, both measured in centimeters, times 0.7854. For containers that do not have indented ends, use the inside height and inside diameter as the dimensions. For metal cans with indented ends (that is, metal cans with ends attached by double seams), consider the height to be the outside height at the double seam minus three-eighths inch (0.953 centimeter) and the diameter to be the outside diameter at the double seam minus one-eighth inch (0.318 centimeter). For fiber-bodied containers with indented ends (that is, fiber-bodied cans with metal ends attached by double seams), consider the height to be the outside height at the double seam minus three-eighths inch (0.953 centimeter) and the diameter to be the outside diameter at the double seam minus three-sixteenths inch (0.476 centimeter).

(iii) Calculate the percent fill of the container as follows: Divide the average volume of nuts found according to paragraph (c)(2)(i) of this section by the appropriate container volume found according to paragraph (c)(2)(ii) of this section and multiply by 100. The result shall be considered to be the percent fill of the container.

(3) If shelled nuts fall below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

§ 164.150 Peanut butter.

(a) Peanut butter is the food prepared by grinding one of the shelled and roasted peanut ingredients provided for by paragraph (b) of this section, to which may be added safe and suitable seasoning and stabilizing ingredients provided for by paragraph (c) of this section, but such seasoning and stabilizing ingredients do not in the aggregate exceed 10 percent of the weight of the finished food. To the ground peanuts, cut or chopped, shelled, and roasted peanuts may be added. During processing, the oil content of the peanut ingredient may be adjusted by the addition or subtraction of peanut oil. The fat content of the finished food shall not exceed 55 percent when determined as prescribed in section 25.004 *Crude Fat—Official, First Action*, paragraph (a) *Direct method*, in "Official Methods of Analysis of the Association of Official Agricultural Chemists," 10th Edition, page 412.

(b) The peanut ingredients referred to in paragraph (a) of this section are:

(1) Blanched peanuts, in which the germ may or may not be included.

(2) Unblanched peanuts, including the skins and germ.

(c) The seasoning and stabilizing ingredients referred to in paragraph (a) of this section are suitable substances which are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act, or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act. Seasoning and stabilizing ingredients that perform a useful function are regarded as suitable, except that artificial flavorings, artificial sweeteners, chemical preservatives, added vitamins and color additives are not suitable ingredients of peanut butter. Oil products used as optional stabilizing ingredients shall be hydrogenated vegetable oils. For the purposes of this section, hydrogenated vegetable oil shall be considered to include partially hydrogenated vegetable oil.

(d) If peanut butter is prepared from unblanched peanuts as specified in paragraph (b)(2) of this section, the name shall show that fact by some such statement as "prepared from unblanched peanuts (skins left on)." Such statement shall appear prominently and conspicuously and shall be in type of the same style and not less than half of the point size of that used for the words "peanut butter." This statement shall immediately precede or follow the words "peanut butter," without intervening written, printed, or graphic matter.

(e) The label of peanut butter shall name, by their common names, the optional ingredients used, as provided in paragraph (c) of this section. If hydrogenated vegetable oil is used, the label statement of optional ingredients shall include the words "Hydrogenated _____ _____ oil" or "Hardened _____ _____ oil", the blank being filled in either with the names of the vegetable sources of the oil or, alternatively, with the word "vegetable"; for example, "Hydrogenated peanut oil" or "Hardened peanut and cottonseed oils" or "Hydrogenated vegetable oil".

PART 165—NONALCOHOLIC BEVERAGES

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Nonalcoholic Beverages

Sec.
165.175 Soda water.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 341, 371) unless otherwise noted.

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Nonalcoholic Beverages

§ 165.175 Soda water.

(a) *Description.* Soda water is the class of beverages made by absorbing carbon dioxide in potable water. The amount of carbon dioxide used is not less than that which will be absorbed by the beverage at a pressure of one atmosphere and at a temperature of 60° F. It either contains no alcohol or only such alcohol, not in excess of 0.5 percent by weight of the finished beverage, as is contributed by the flavoring ingredient used. Soda water designated by any name which includes the word "cola" or "pepper" shall contain caffeine from kola nut extract and/or other natural caffeine-containing extracts. Caffeine may also be added to any soda water. The total caffeine content in the finished food shall not exceed 0.02 percent by weight. Soda water may contain any safe and suitable optional ingredient, except that vitamins, minerals, and proteins added for nutritional purposes and artificial sweeteners are not suitable for food encompassed by this standard.

(b) *Nomenclature.* (1) The name of the beverage for which a definition and standard of identity is established by this section, which is neither flavored nor sweetened, is soda water, club soda, or plain soda.

(2) The name of each beverage containing flavoring and sweetening ingredients shall appear as "_____ soda" or "_____ water" or "_____ carbonated beverage", the blank to contain the word or words that designate the characterizing flavor of the soda water as prescribed in § 101.22 of this chapter.

(3) If the soda water is one generally designated by a particular common name; for example, ginger ale, root beer, or sparkling water, that name may be used in lieu of the name prescribed in paragraph (b)(1) and (2) of this section. For the purposes of this section, a proprietary name that is commonly used by the public as the designation of a particular kind of soda water may be used in lieu of the name prescribed in paragraph (b)(1) and (2) of this section.

(c) *Label declaration.* Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

PART 166—MARGARINE

Subpart A—General Provisions

Sec.
Sec.
166.40 Labeling of margarine.

Subpart B—Requirements for Specific Standardized Margarine

166.110 Margarine.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 341, 371), unless otherwise noted.

Subpart A—General Provisions

§ 166.40 Labeling of margarine.

The Federal Food, Drug, and Cosmetic Act was amended by Public Law 459, 81st Congress (64 Stat. 20) on colored oleomargarine or margarine by adding thereto a new section numbered 407. Among other things, this section requires that there appear on the label of the package the word "oleomargarine" or "margarine" in type or lettering at least as large as any other type or lettering on the label, and a full and accurate statement of all the ingredients contained in such oleomargarine or margarine. It provides that these requirements "shall be in addition to and not in lieu of any of the other requirements of this Act".

(a) Under section 403(g) of the Federal Food, Drug, and Cosmetic Act, any

article that is represented as or purports to be oleomargarine or margarine must conform to the definition and standard of identity for oleomargarine or margarine promulgated under section 401 of the act (Subpart B of this part), and its label must bear the name "oleomargarine" or "margarine".

(b) The identity standard for oleomargarine or margarine applies to both the uncolored and the colored article. Although this standard does not require that all permitted optional ingredients be declared on the label, the amendment to the Federal Food, Drug, and Cosmetic Act made by Public Law 459, 81st Congress, requires the labels on packages of colored oleomargarine or margarine to bear "a full and accurate statement of all the ingredients contained in such oleomargarine or margarine". The optional ingredients permitted by the identity standard for oleomargarine or margarine and the names by which we believe such ingredients, when present, should be declared in order to constitute "a full and accurate statement" are set forth below:

(1) The rendered fat or oil, or stearin derived therefrom (any or all of which may be hydrogenated), of cattle, sheep, swine, or goats, or any combination of two or more such articles—to be declared by the name of the specific animal fat, oil, or stearin, for example, "beef fat". If the animal fat or oil is hydrogenated the name should include the word "hydrogenated" or "hardened". Where combinations are used, the names are to be arranged in order of predominance, with the animal fat, oil, or stearin present in greatest proportion named first.

(2) Any vegetable food fat or oil, or oil or stearin derived therefrom (any or all of which may be hydrogenated), or any combination of two or more such articles—to be declared by the name of the specific vegetable food fat, oil, or stearin, for example "cottonseed oil" or "soybean oil". If the vegetable fats or oils present are hydrogenated, the declaration should include the word "hydrogenated" or "hardened", for example, "hydrogenated cottonseed oil" or "hardened cottonseed oil". If two or more vegetable food fats or oils are used they are to be named in order of predominance with the one present in greatest proportion named first in the series, as, for example, "cottonseed oil, soybean oil, and corn oil".

(3) The optional ingredients cream, milk, skim milk, nonfat dry milk and water, ground soybeans and water, butter, and salt should be declared by those terms.

(4) Artificial color and artificial flavor should be declared as such by the terms prescribed in the identity standard for oleomargarine or margarine (Subpart B of this part). They need not be declared additionally by the names of the specific colors or flavors.

(5) The presence of sodium benzoate or benzoic acid should be declared as prescribed by the identity standard for oleomargarine or margarine.

(6) The optional ingredient vitamin A added in an essential carrier should be declared as "vitamin A added" or "with added vitamin A".

(7) The optional ingredient vitamin D should be declared as "vitamin D added" or "with added vitamin D".

(8) The optional emulsifying ingredients lecithin, mono- or diglycerides and sodium sulfo-acetate derivatives of mono- or diglycerides should be declared by those terms.

(9) The presence of citric acid, isopropyl citrate, and stearyl citrate should be declared as prescribed by the identity standard for oleomargarine or margarine.

(10) The statement of all the ingredients contained in colored olemargarine or colored margarine is subject to the requirements pertaining to conspicuousness in section 403 (f) of the act.

(c) In considering the requirement that the word "oleomargarine" or "margarine" be in type or lettering at least as large as any other type or lettering on the label, it must be borne in mind that at least three factors are involved—the height of each letter, the area occupied by each letter as measured by a closely fitting rectangle drawn around it, and the boldness of letters or breadth of the lines forming the letters. The type or lettering used should meet the following tests:

(1) The height of each letter in the word "oleomargarine" or "margarine" should equal or exceed the height of any other letter elsewhere on the label.

(2) The area of the closely fitting rectangle with respect to any of the letters in the word "oleomargarine" or "margarine" should equal or exceed the area of such rectangle applied to the same or a corresponding letter elsewhere on the label.

(3) The letters in the word "oleomargarine" or "margarine" should be equal to or exceed in prominence and boldness, such as breadth of lines forming the letters, the same or corresponding letters elsewhere on the label.

(d) [Reserved]

(e) The word "oleomargarine" or "margarine" (and thus the other information called for by the statute) should appear on each panel of the package label that might reasonably be selected by the grocer for display purposes at the point of sale.

(f) The amendment covering colored oleomargarine or colored margarine states that, "for the purposes of * * * section 407 of the Federal Food, Drug, and Cosmetic Act, as amended, the term 'oleomargarine' or 'margarine' includes: (1) All substances, mixtures, and compounds known as oleomargarine or margarine; (2) all substances, mixtures, and compounds which have a consistence similar to that of butter and which contain any edible oils or fats other than milk fat if made in imitation or semblance of butter". Notwithstanding the difference between this definition and the definition and standard of identity for oleomargarine or margarine promulgated under section 401 of the act, it was the clear intent of Congress that any article which is represented as or purports to be oleomargarine or margarine is misbranded if it fails to comply with the definition and standard of identity for oleomargarine or margarine even though it may meet the statutory definition.

(g) Section 407(a) states that "Colored oleomargarine or colored margarine which is sold in the same State or Territory in which it is produced shall be subject in the same manner and to the same extent to the provisions of this act as if it had been introduced in interstate commerce".

(h) Section 407(b)(4) requires that each part of the contents of the package be "contained in a wrapper which bears the word 'oleomargarine' or 'margarine' in type or lettering not smaller than 20-point type". The Food and Drug Administration interprets this to mean that the height of the actual letters is no less than 20 points, or 20/72 of 1 inch.

(i) The wrappers on the subdivisions of oleomargarine or margarine contained within the package sold at retail are labels within the meaning of section 201(k) and shall contain all of the label information required by sections 403 and 407 of the Federal Food, Drug, and Cosmetic Act, just as in the case of 1-pound cartons, except that wrappers on the subdivisions contained within the retail package shall be exempt from the requirements for label declaration of ingredients of section 403(g)(2), (i)(2), and (k) of the act when the subdivisions are securely enclosed within and are not intended to be separated from the retail package under conditions of retail sale, the wrappers on the subdivisions are labeled with the statement "This Unit Not Labeled For Retail Sale" in type size not less than one-sixteenth inch in height, and each multiunit package principal display panel is labeled with the statement "Inner Units Not Labeled for Retail Sale" in type size not smaller than the minimum size required for the declaration of net quantity of contents by § 101.105 of this chapter.

(Sec. 407, 64 Stat. 20 (21 U.S.C. 347).)

Subpart B—Requirements for Specific Standardized Margarine

§ 166.110 Margarine.

(a) Margarine (or oleomargarine) is the food in plastic form or liquid emulsion, containing not less than 80 percent fat determined by the method prescribed under section 16.163 of the "Indirect Method," "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th edition 1970.[2] Margarine contains only safe and suitable ingredients. It is produced from one or more of the optional ingredients in paragraph (a) (1) of this section, and one or more of the optional ingredients in subparagraph (a) (2) of this section, to which may be added one or more of the optional ingredients in paragraph (b) of this section. Margarine contains vitamin A as provided for in paragraph (a)(3) of this section.

(1) Edible fats and/or oils, or mixtures of these, whose origin is vegetable or rendered animal carcass fats, any or all of which may have been subjected to an accepted process of physico-chemical modification. They may contain small amounts of other lipids such as phosphatides, or unsaponifiable constituents and of free fatty acids naturally present in the fat or oil.

(2) One or more of the following aqueous phase ingredients:

(i) Water and/or milk and/or milk products.

(ii) Suitable edible protein including, but not limited to, the liquid, condensed, or dry form of whey, whey modified by the reduction of lactose and/or minerals, nonlactose containing whey components, albumin, casein, caseinate, vegetable proteins, or soy protein isolate, in amounts not greater than reasonably required to accomplish the desired effect.

(iii) Any mixture of two or more of the articles named under paragraph (a)(2)(i) and (ii) of this section.

(iv) The ingredients in paragraph (a)(2)(i), (ii), (iii) of this section shall be pasteurized and then may be subjected to the action of harmless bacterial starters. One or more of the articles designated in paragraph (a)(2)(i), (ii), (iii) of this section is intimately mixed with the edible fat and/or oil ingredients to form a solidified or liquid emulsion.

(3) Vitamin A in such quantity that the finished margarine contains not less than 15,000 international units per pound.

(b) Optional ingredients: (1) Vitamin D in such quantity that the finished oleomargarine contains not less than 1,500 international units of vitamin D per pound.

(2) Salt (sodium chloride); potassium chloride for dietary margarine or oleomargarine.

(3) Nutritive carbohydrate sweeteners.

(4) Emulsifiers including but not limited to the following within these maximum amounts in percent by weight of the finished food: Mono- and diglycerides of fatty acids esterified with the following acids; acetic, acetyltartaric, citric, lactic, tartaric, and their sodium and calcium salts, 0.5 percent; such mono- and diglycerides in combination with the sodium sulfo-acetate derivatives thereof, 0.5 percent; polyglycerol esters of fatty acids, 0.5 percent; 1,2-propylene glycol esters of fatty acids, 2 percent; lecithin, 0.5 percent.

(5) Preservatives including but not limited to the following within these maximum amounts in percent by weight of the finished food: Sorbic acid, benzoic acid and their sodium, potassium, and calcium salts, individually, 0.1 percent, or in combination, 0.2 percent, expressed as the acids; calcium disodium EDTA, 0.0075 percent, propyl, octyl, and dodecyl gallates, BHT, BHA, ascorbyl palmitate, ascorbyl stearate, all individually or in combination, 0.02 percent, stearyl citrate, 0.15 percent; isopropyl citrate mixture, 0.02 percent.

(6) Color additives. For the purpose of this subparagraph, provitamin A (beta-carotene) shall be deemed to be a color additive.

(7) Flavoring substances. If the flavoring ingredients impart to the food a flavor other than in semblance of butter, the characterizing flavor shall be declared as part of the name of the food in accordance with § 101.22 of this chapter.

(8) Acidulants.

(9) Alkalizers.

(c) The name of the food for which a definition and standard of identity are prescribed in this section is "margarine" or "oleomargarine".

(d) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter. For the purposes of this section the use of the term "milk" unqualified means milk from cows. If any milk other than cow's milk is used in whole or in part, the animal source shall be identified in conjunction with the word milk in the ingredient statement. Colored margarine shall be subject to the provisions of section 407 of the Federal Food, Drug, and Cosmetic Act as amended.

PART 168—SWEETENERS AND TABLE SIRUPS

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Sweeteners and Table Sirups

Sec.

168.110 Dextrose anhydrous.
168.111 Dextrose monohydrate.
168.120 Glucose sirup.
168.121 Dried glucose sirup.
168.122 Lactose.
168.130 Cane sirup.
168.140 Maple sirup.
168.160 Sorghum sirup.
168.180 Table sirup.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046, as amended, 1055–1056, as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 341, 371).

Subpart A—[Reserved]

Subpart B—Requirements for Specific Standardized Sweeteners and Table Sirups

§ 168.110 Dextrose anhydrous.

(a) Dextrose anhydrous is purified and crystallized D-glucose without water of crystallization and conforms to the specifications of § 168.111, except that the total solids content is not less than 98.0 percent m/m.

(b) The name of the food is "Dextrose anhydrous" or "Anhydrous dextrose".

§ 168.111 Dextrose monohydrate.

(a) Dextrose monohydrate is purified and crystallized D-glucose containing one molecule of water of crystallization with each molecule of D-glucose.

(b) The food shall meet the following specifications:

(1) The total solids content is not less than 90.0 percent mass/mass (m/m), and the reducing sugar content (dextrose equivalent), expressed as D-glucose, is not less than 99.5 percent m/m calculated on a dry basis.

(2) The sulfated ash content is not more than 0.25 percent m/m (calculated on a dry basis), and the sulfur dioxide content is not more than 20 mg/kg.

(c) The name of the food is "Dextrose monohydrate" or Dextrose".

(d) For purposes of this section, the methods of analysis to be used to determine if the food meets the specifications of paragraph (b)(1) and (2) of this section are the following sections in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., 1970.[2]

(1) Total solids content, 31.005.

(2) Reducing sugar content, 31.212(a).

(3) Sulfated ash content, 31.208.

(4) Sulfur dioxide content, 20.090–20.095.

§ 168.120 Glucose sirup.

(a) Glucose sirup is the purified, concentrated, aqueous solution of nutritive saccharides obtained from edible starch.

(b) The food shall meet the following specifications:

(1) The total solids content is not less than 70.0 percent mass/mass (m/m), and the reducing sugar content (dextrose equivalent), expressed as D-glucose, is not less than 20.0 percent m/m calculated on a dry basis.

(2) The sulfated ash content is not more than 1.0 percent m/m (calculated on a dry basis), and the sulfur dioxide content is not more than 40 mg/kg.

(c) The name of the food is "Glucose sirup". When the food is derived from a specific type of starch, the name may alternatively be "_____ sirup", the blank to be filled in with the name of the starch. For example, "Corn sirup", "Wheat sirup", "Tapioca sirup". When the starch is derived from sorghum grain, the alternative name of the food is "Sorghum grain sirup". The word "sirup" may also be spelled "syrup".

(d) For purposes of this section, the methods of analysis to be used to determine if a food meets the specifications of paragraph (b)(1) and (2) of this section are the following sections in "Official Methods of Analysis of the Association of Official Analytical Chemists", 11th Ed., 1970:[2]

(1) Total solids content, 31.200–31.201.

(2) Reducing sugar content, 31.212(a).

(3) Sulfated ash content, 31.208.

(4) Sulfur dioxide content, 20.090–20.095.

§ 168.121 Dried glucose sirup.

(a) Dried glucose sirup is glucose sirup from which the water has been partially removed and conforms to the specifications of § 168.120, except that:

(1) The total solids content is not less than 90.0 percent m/m when the reducing sugar content (dextrose equivalent), expressed as D-glucose, is not less than 88.0 percent m/m, calculated on a dry basis; or

(2) The total solids content is not less than 93.0 percent m/m when the reducing sugar content, (dextrose equivalent) expressed as D-glucose, is less than 88.0 percent m/m, calculated on a dry basis.

(b) The name of the food is "Dried glucose sirup" or "Glucose sirup solids".

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[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

When the food is derived from a specific type of starch, the name may alternatively be "Dried _____ sirup" or "_____ sirup solids", the blank to be filled in with the name of the starch; for example, "Dried corn sirup", "Corn sirup solids", Dried wheat sirup", "Wheat sirup solids", "Dried tapioca sirup", "Tapioca sirup solids". When the starch is derived from sorghum grain, the alternative name of the food is "Dried sorghum grain sirup" or "Sorghum grain sirup solids". The word "sirup" may also be spelled "syrup".

§ 168.122 Lactose.

(a) Lactose is the carbohydrate normally obtained from whey. It may be anhydrous or contain one molecule of water of crystallization or be a mixture of both forms.

(b) The food shall meet the following specifications:

(1) The lactose content is not less than 99.0 percent, mass over mass (m/m), calculated on a dry basis.

(2) The sulfated ash content is not more than 0.3 percent, m/m, calculated on a dry basis.

(3) The pH of a 10.0 percent, m/m, solution is not less than 4.5 nor more than 7.0.

(4) The loss on drying for 16 hours at 120° C is not more than 6.0 percent, m/m.

(c) The name of the food is "Lactose" or, alternatively, "Milk sugar".

(d) (1) The methods of analysis to be used to determine whether the food meets the requirements of paragraph (b) (1), (2), and (3) of this section are the following sections in "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th ed., 1975: [1]

(i) Lactose content, section 31.062.

(ii) Sulfated ash content, section 31.014.

(iii) pH, section 14.022, except that a 10.0 percent, m/m, solution of lactose in water is used for the determination.

(2) The method of analysis to be used to determine if the food meets the requirement of paragraph (b) (4) of this section is the following: Loss on drying at 120° C, "United States Pharmacopeia," 18th Revision, 1970, pages 358 and 935.

§ 168.130 Cane sirup.

(a) Cane sirup is the liquid food derived by concentration and heat treatment of the juice of sugarcane (*Saccharum officinarum* L.) or by solution in water of sugarcane concrete made from such juice. It contains not less than 74 percent by weight of soluble solids derived solely from such juice. The concentration may be adjusted with or without added water. It may contain one or more of the optional ingredients provided for in paragraph (b) of this section. All ingredients from which the food is fabricated shall be safe and suitable.

(b) The optional ingredients that may be used in cane sirup are:

(1) Salt.

(2) Preservatives.

(3) Defoaming agents.

(c) The name of the food is "Cane sirup" or "Sugar cane sirup". Alternatively, the word "sirup" may be spelled "syrup".

(d) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 168.140 Maple sirup.

(a) Maple sirup is the liquid food derived by concentration and heat treatment of the sap of the maple tree (*Acer*) or by solution in water of maple sugar (maple concrete) made from such sap. It contains not less than 66 percent by weight of soluble solids derived solely from such sap. The concentration may be adjusted with or without added water. It may contain one or more of the optional ingredients provided for in paragraph (b) of this section. All ingredients from which the food is fabricated shall be safe and suitable.

(b) The optional ingredients that may be used in maple sirup are:

(1) Salt.

(2) Chemical preservatives.

(3) Defoaming agents.

(c) The name of the food is "Maple sirup". Alternatively, the word "sirup" may be spelled "syrup".

(d) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 168.160 Sorghum sirup.

(a) Sorghum sirup is the liquid food derived by concentration and heat treatment of the juice of sorghum cane (sorgos) (*Sorghum vulgare*). It contains not less than 74 percent by weight of soluble solids derived solely from such juice. The concentration may be adjusted with or without added water. It may contain one or more of the optional ingredients provided for in paragraph (b) of this section. All ingredients from which the food is fabricated shall be safe and suitable.

(b) The optional ingredients that may be used in sorghum sirup are:

(1) Salt.

(2) Chemical preservatives.

(3) Defoaming agents.

(4) Enzymes.

(5) Anticrystallizing agents.

(6) Antisolidifying agents.

(c) The name of the food is "Sorghum sirup" or "Sorghum". Alternatively, the word "sirup" may be spelled "syrup".

(d) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 168.180 Table sirup.

(a) Table sirup is the liquid food consisting of one or more of the optional sweetening ingredients provided for in paragraph (b) (1) of this section. The food contains not less than 65 percent soluble sweetener solids by weight and is prepared with or without added water. It may contain one or more of the optional ingredients prescribed in paragraphs (b) (2) through (12) of this section. All ingredients from which the food is fabricated shall be safe and suitable. (Vitamins, minerals, and protein added for nutritional purposes and artificial sweeteners are not considered to be suitable ingredients for this food.)

(b) The optional ingredients that may be used in table sirup are:

(1) One or more of the nutritive carbohydrate sweeteners provided for in this paragraph (b) (1). When a sweetener provided for in paragraph (b) (1) (i) or (ii) of this section is used it shall constitute not less than 2 percent by weight of the finished food.

(i) The sirups identified by §§ 168.130, 168.140, and 168.160, except that the use of any such ingredient is so limited that the finished food does not meet the requirement prescribed for any sirup by §§ 168.130, 168.140, or 168.160.

(ii) Honey.

(iii) Other nutritive carbohydrate sweeteners.

(2) Butter, in a quantity not less than 2 percent by weight of the finished food.

(3) Edible fats and oils, except that, in products designated as "buttered sirups", butter as provided for in paragraph (b) (2) of this section is the only fat that may be used.

(4) Emulsifiers or stabilizers or both.

(5) Natural and artificial flavorings, either fruit or nonfruit, alone or in carriers.

(6) Color additives.

(7) Salt.

(8) Chemical preservatives.

(9) Viscosity adjusting agents.

(10) Acidifying, alkalizing, or buffering agents.

(11) Defoaming agents.

(12) Any other ingredient (e.g., shredded coconut, ground orange peel) that is not incompatible with other ingredients in the food.

(c) Except as provided for in this paragraph and in paragraph (d) (2) and (3) of this section, the name of the food is "Table sirup", "Sirup", "Pancake sirup", "Waffle sirup", "Pancake and waffle sirup", or "_____ sirup", the blank being filled in with the word or words that designate the sweetening ingredient that characterizes the food, except "maple", "cane", or "sorghum" alone, such sirups being required to comply in all respects with §§ 168.130, 168.140, and 168.160, respectively, and in the case of more than one sweetening ingredient, in descending order of predominance by weight in the food. The type shall be of uniform style and size.

(1) When one of the sweeteners constitutes at least 80 percent of the total sweetener solids, the name of the food may be designated as the corresponding sirup, for example, "Corn sirup", provided that the name is immediately and conspicuously followed, without intervening written, printed, or graphic matter, by the statement "with _____" as part of the name, the blank being filled in with the name or names of each additional sweetening ingredient present, stated in a clear legible manner in letters of uniform style and size not less than one-half the height of, nor larger than, the letters used in the name of the principal sweetener.

(2) When butter is used, as provided for in paragraph (b)(2) of this section, the name of the food may be "Buttered ----------", the blank being filled in with the name otherwise prescribed in this paragraph. The percentage by weight of butter present shall be declared as part of the name of the food as prescribed by Part 102 of this chapter.

(3) Alternatively, the word "sirup" may be spelled "syrup".

(d)(1) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(2) A statement (other than in the ingredient listing) or a vignette identifying a flavor may be included on the label only if such flavor contributes the primary recognizable flavor that characterizes the sirup. When maple, honey, or both maple and honey are represented as the characterizing flavors, the total quantity of maple sirup or honey, singly, or of maple sirup and honey in combination, shall be not less than 10 percent by weight of the finished food. The presence of any natural or artificial flavor in the food shall be declared on the label as prescribed by the applicable sections of Part 101 of this chapter.

(3) The percentage of any optional ingredient used shall be declared as part of the name of the food as prescribed by Part 102 of this chapter when all of the following conditions apply to the use of the ingredient:

(i) It is one of the characterizing ingredients permitted by paragraph (b)(1)(i) and (ii) of this section.

(ii) The ingredient is either named on the label other than in the list of ingredients or is suggested by vignette or other labeling.

PART 169—FOOD DRESSINGS AND FLAVORINGS

Subpart A—General Provisions

Sec.
169.3 Definitions.

Subpart B—Requirements for Specific Standardized Food Dressings and Flavorings

169.115 French dressing.
169.140 Mayonnaise.
169.150 Salad dressing.
169.175 Vanilla extract.
169.176 Concentrated vanilla extract.
169.177 Vanilla flavoring.
169.178 Concentrated vanilla flavoring.
169.179 Vanilla powder.
169.180 Vanilla-vanillin extract.
169.181 Vanilla-vanillin flavoring.
169.182 Vanilla-vanillin powder.

AUTHORITY: Secs. 401, 701, 52 Stat. 1046 as amended, 1055–1056, as amended by 70 Stat. 919 (21 U.S.C. 341, 371) unless otherwise noted.

Subpart A—General Provisions

§ 169.3 Definitions.

For the purposes of this part:

(a) The term "vanilla beans" means the properly cured and dried fruit pods of *Vanilla planifolia Andrews* and of *Vanilla tahitensis Moore*.

(b) The term "unit weight of vanilla beans" means, in the case of vanilla beans containing not more than 25 percent moisture, 13.35 ounces of such beans; and, in the case of vanilla beans containing more than 25 percent moisture, it means the weight of such beans equivalent in content of moisture-free vanilla-bean solids to 13.35 ounces of vanilla beans containing 25 percent moisture. (For example, one unit weight of vanilla beans containing 33.25 percent moisture amounts to 15 ounces.) The moisture content of vanilla beans is determined by the method prescribed in Official Methods of Analysis of the Association of Official Agricultural Chemists, Ninth Edition, 1960, sections 22.004 and 22.005 [Ed. note, 10th edition, 1965, p. 327, secs. 22.004, 22.005], except that the toluene used is blended with 20 percent by volume of benzene and the total distillation time is 4 hours. To prepare samples for analysis, the pods are chopped into pieces approximately ¼-inch in longest dimension, using care to avoid moisture change.

(c) The term "unit of vanilla constituent" means the total sapid and odorous principles extractable from one unit weight of vanilla beans, as defined in paragraph (b) of this section, by an aqueous alcohol solution in which the content of ethyl alcohol by volume amounts to not less than 35 percent.

Subpart B—Requirements for Specific Standardized Food Dressings and Flavorings

§ 169.115 French dressing.

(a) *Description.* French dressing is the separable liquid food or the emulsified viscous fluid food prepared from vegetable oil(s) and one or both of the acidifying ingredients specified in paragraph (b) of this section. One or more of the ingredients specified in paragraph (c) of this section may also be used. The vegetable oil(s) used may contain an optional crystallization inhibitor as specified in paragraph (c)(11) of this section. All the ingredients from which the food is fabricated shall be safe and suitable. French dressing contains not less than 35 percent by weight of vegetable oil. French dressing may be mixed and packed in an atmosphere in which air is replaced in whole or in part by carbon dioxide or nitrogen.

(b) *Acidifying ingredients.* (1) Any vinegar or any vinegar diluted with water, or any such vinegar or diluted vinegar mixed with an optional acidifying ingredient as specified in paragraph (c)(9) of this section. For the purpose of this paragraph, any blend of two or more vinegars is considered to be a vinegar.

(2) Lemon juice and/or lime juice in any appropriate form, which may be diluted with water.

(c) *Other optional ingredients.* The following optional ingredients may also be used:

(1) Salt.

(2) Nutritive carbohydrate sweeteners.

(3) Spices and/or natural flavorings.

(4) Monosodium glutamate.

(5) Tomato paste, tomato puree, catsup, sherry wine.

(6) Eggs and ingredients derived from eggs.

(7) Color additives that will impart the color traditionally expected.

(8) Stabilizers and thickeners to which calcium carbonate or sodium hexametaphosphate may be added. Dioctyl sodium sulfosuccinate may be added in accordance with § 172.810 of this chapter.

(9) Citric and/or malic acid, in an amount not greater than 25 percent of the weight of the acids of the vinegar or diluted vinegar calculated as acetic acid.

(10) Sequestrant(s), including but not limited to calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate) and/or disodium EDTA (disodium ethylenediaminetetraacetate), may be used to preserve color and/or flavor.

(11) Crystallization inhibitors, including but not limited to oxystearin, lecithin, or polyglycerol esters of fatty acids.

(d) *Nomenclature.* The name of the food is "French dressing".

(e) *Label declaration of ingredients.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 169.140 Mayonnaise.

(a) *Description.* Mayonnaise, mayonnaise dressing, is the emulsified semisolid food prepared from vegetable oil(s), one or both of the acidifying ingredients specified in paragraph (b) of this section, and one or more of the egg yolk-containing ingredients specified in paragraph (c) of this section. One or more of the ingredients specified in paragraph (d) of this section may also be used. The vegetable oil(s) used may contain an optional crystallization inhibitor as specified in paragraph (d)(7) of this section. All the ingredients from which the food is fabricated shall be safe and suitable. Mayonnaise contains not less than 65 percent by weight of vegetable oil. Mayonnaise may be mixed and packed in an atmosphere in which air is replaced in whole or in part by carbon dioxide or nitrogen.

(b) *Acidifying ingredients.* (1) Any vinegar or any vinegar diluted with water to an acidity, calculated as acetic acid, of not less than 2½ percent by weight, or any such vinegar or diluted vinegar mixed with an optional acidifying ingredient as specified in paragraph (d)(6) of this section. For the purpose of this paragraph, any blend of two or more vinegars is considered to be a vinegar.

(2) Lemon juice and/or lime juice in any appropriate form, which may be diluted with water to an acidity, calculated as citric acid, of not less than 2½ percent by weight.

(c) *Egg yolk-containing ingredients.* Liquid egg yolks, frozen egg yolks, dried egg yolks, liquid whole eggs, frozen whole eggs, dried whole eggs, or any one or more of the foregoing ingredients listed in this paragraph with liquid egg white or frozen egg white.

(d) *Other optional ingredients.* The following optional ingredients may also be used:

(1) Salt.

(2) Nutritive carbohydrate sweeteners.

(3) Any spice (except saffron or turmeric) or natural flavoring, provided it does not impart to the mayonnaise a color simulating the color imparted by egg yolk.

(4) Monosodium glutamate.

(5) Sequestrant(s), including but not limited to calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate) and/or disodium EDTA (disodium ethylenediaminetetraacetate), may be used to preserve color and/or flavor.

(6) Citric and/or malic acid in an amount not greater than 25 percent of the weight of the acids of the vinegar or diluted vinegar, calculated as acetic acid.

(7) Crystallization inhibitors, including but not limited to oxystearin, lecithin, or polyglycerol esters of fatty acids.

(e) *Nomenclature.* The name of the food is "Mayonnaise" or "Mayonnaise dressing".

(f) *Label declaration of ingredients.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 169.150 Salad dressing.

(a) *Description.* Salad dressing is the emulsified semisolid food prepared from vegetable oil(s), one or both of the acidifying ingredients specified in paragraph (b) of this section, one or more of the egg yolk-containing ingredients specified in paragraph (c) of this section, and a cooked or partly cooked starchy paste prepared as specified in paragraph (d) of this section. One or more of the ingredients in paragraph (e) of this section may also be used. The vegetable oil(s) used may contain an optional crystallization inhibitor as specified in paragraph (e)(8) of this section. All the ingredients from which the food is fabricated shall be safe and suitable. Salad dressing contains not less than 30 percent by weight of vegetable oil and not less egg yolk-containing ingredient than is equivalent in egg yolk solids content to 4 percent by weight of liquid egg yolks. Salad dressing may be mixed and packed in an atmosphere in which air is replaced in whole or in part by carbon dioxide or nitrogen.

(b) *Acidifying ingredients.* (1) Any vinegar or any vinegar diluted with water, or any such vinegar or diluted vinegar mixed with an optional acidifying ingredient as specified in paragraph (e)(6) of this section. For the purpose of this paragraph, any blend of two or more vinegars is considered to be a vinegar. .

(2) Lemon juice and/or lime juice in any appropriate form, which may be diluted with water.

(c) *Egg yolk-containing ingredients.* Liquid egg yolks, frozen egg yolks, dried egg yolks, liquid whole eggs, frozen whole eggs, dried whole eggs, or any one of more of the foregoing ingredients listed in this paragraph with liquid egg white or frozen egg white.

(d) *Starchy paste.* It may be prepared from a food starch, food starch-modified, tapioca flour, wheat flour, rye flour, or any two or more of these. Water may be added in the preparation of the paste.

(e) *Other optional ingredients.* The following optional ingredients may also be used.

(1) Salt.

(2) Nutritive carbohydrate sweeteners.

(3) Any spice (except saffron or turmeric) or natural flavoring, provided it does not impart to the salad dressing a color simulating the color imparted by egg yolk.

(4) Monosodium glutamate.

(5) Stabilizers and thickeners. Dioctyl sodium sulfosuccinate may be added in accordance with § 172.810 of this chapter.

(6) Citric and/or malic acid may be used in an amount not greater than 25 percent of the weight of the acids of the vinegar or diluted vinegar calculated as acetic acid.

(7) Sequestrant(s), including but not limited to calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate) and/or disodium EDTA (disodium ethylenediaminetetraactetate), may be used to preserve color and/or flavor.

(8) Crystallization inhibitors, including but not limited to oxystearin, lecithin, or polyglycerol esters of fatty acids.

(f) *Nomenclature.* The name of the food is "Salad dressing".

(g) *Label declaration of optional ingredients.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 169.175 Vanilla extract.

(a) Vanilla extract is the solution in aqueous ethyl alcohol of the sapid and odorous principles extractable from vanilla beans. In vanilla extract the content of ethyl alcohol is not less than 35 percent by volume and the content of vanilla constituent, as defined in § 169.3(c), is not less than one unit per gallon. The vanilla constituent may be extracted directly from vanilla beans or it may be added in the form of concentrated vanilla extract or concentrated vanilla flavoring or vanilla flavoring concentrated to the semisolid form called vanilla oleoresin. Vanilla extract may contain one or more of the following optional ingredients:

(1) Glycerin.

(2) Propylene glycol.

(3) Sugar (including invert sugar).

(4) Dextrose.

(5) Corn sirup (including dried corn sirup).

(b)(1) The specified name of the food is "Vanilla extract" or "Extract of vanilla".

(2) When the vanilla extract is made in whole or in part by dilution of vanilla oleoresin, concentrated vanilla extract, or concentrated vanilla flavoring, the label shall bear the statement "Made from _____" or "Made in part from _____", the blank being filled in with the name or names "vanilla oleoresin", "concentrated vanilla extract", or "concentrated vanilla flavoring", as appropriate. If the article contains two or more units of vanilla constituent, the name of the food shall include the designation "_____ fold", the blank being filled in with the whole number (disregarding fractions) expressing the number of units of vanilla constituent per gallon of the article.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the labeling required by paragraph (b)(2) of this section shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 169.176 Concentrated vanilla extract.

(a) Concentrated vanilla extract conforms to the definition and standard of identity and is subject to any requirement for label statement of optional ingredients prescribed for vanilla extract by § 169.175, except that it is concentrated to remove part of the solvent, and each gallon contains two or more units of vanilla constituent as defined in § 169.3(c). The content of ethyl alcohol is not less than 35 percent by volume.

(b) The specified name of the food is "Concentrated vanilla extract _____ fold" or "_____ fold concentrated vanilla extract", the blank being filled in with the whole number (disregarding fractions) expressing the number of units of vanilla constituent per gallon of the article. (For example, "Concentrated vanilla extract 2-fold".)

§ 169.177 Vanilla flavoring.

(a) Vanilla flavoring conforms to the definition and standard of identity and is subject to any requirement for label statement of optional ingredients prescribed for vanilla extract by § 169.175, except that its content of ethyl alcohol is less than 35 percent by volume.

(b) The specified name of the food is "Vanilla flavoring".

§ 169.178 Concentrated vanilla flavoring.

(a) Concentrated vanilla flavoring conforms to the definition and standard of identity and is subject to any requirement for label statement of optional ingredients prescribed for vanilla flavoring by § 169.177, except that it is concentrated to remove part of the solvent, and each gallon contains two or more units of vanilla constituent as defined in § 169.3(c).

(b) The specified name of the food is "Concentrated vanilla flavoring _____ fold" or "_____ fold concentrated vanilla flavoring", the blank being filled in with the whole number (disregarding fractions) expressing the number of units of vanilla constituent per gallon of the article. (For example, "Concentrated vanilla flavoring 3-fold".)

§ 169.179 Vanilla powder.

(a) Vanilla powder is a mixture of ground vanilla beans or vanilla oleoresin or both, with one or more of the following optional blending ingredients:

(1) Sugar.

(2) Dextrose.

(3) Lactose.

(4) Food starch (including food starch-modified as prescribed in § 172.892 of this chapter).

(5) Dried corn sirup.

(6) Gum acacia.

Vanilla powder may contain one or any mixture of two or more of the anticaking ingredients specified in paragraph (b) of this section, but the total weight of any such ingredient or mixture is not more than 2 percent of the weight of the finished vanilla powder. Vanilla powder contains in each 8 pounds not less than one unit of vanilla constituent, as defined in § 169.3(c).

(b) The anticaking ingredients referred to in paragraph (a) of this section are:

(1) Aluminum calcium silicate.
(2) Calcium silicate.
(3) Calcium stearate.
(4) Magnesium silicate.
(5) Tricalcium phosphate.

(c)(1) The specified name of the food is "Vanilla powder _____ fold" or "_____ fold vanilla powder", except that if sugar is the optional blending ingredient used, the word "sugar" may replace the word "powder". The blank in the name is filled in with the whole number (disregarding fractions) expressing the number of units of vanilla constituent per 8 pounds of the article. However, if the strength of the article is less than 2-fold, the term "_____ fold" is omitted from the name.

(2) The label of vanilla powder shall bear the common names of any of the optional ingredients specified in paragraphs (a) and (b) of this section that are used, except that where the alternative name "Vanilla sugar" is used for designating the food it is not required that sugar be named as an optional ingredient.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the labeling required by paragraph (c)(2) of this section shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 169.180 Vanilla-vanillin extract.

(a) Vanilla-vanillin extract conforms to the definition and standard of identity and is subject to any requirement for label statement of optional ingredients prescribed for vanilla extract by § 169.175, except that for each unit of vanilla constituent, as defined in § 169.3(c), contained therein, the article also contains not more than 1 ounce of added vanillin.

(b) The specified name of the food is "Vanilla-vanillin extract _____ fold" or "_____ fold vanilla-vanillin extract", followed immediately by the statement "contains vanillin, an artificial flavor (or flavoring)". The blank in the name is filled in with the whole number (disregarding fractions) expressing the sum of the number of units of vanilla constituent plus the number of ounces of added vanillin per gallon of the article. However, if the strength of the article is less than 2-fold, the term "_____ fold" is omitted from the name.

§ 169.181 Vanilla-vanillin flavoring.

(a) Vanilla-vanillin flavoring conforms to the definition and standard of identity and is subject to any requirement for label statement of optional ingredients prescribed for vanilla-vanillin extract by § 169.180, except that its content of ethyl alcohol is less than 35 percent by volume.

(b) The specified name of the food is "Vanilla-vanillin flavoring _____ fold" or "_____ fold vanilla-vanillin flavoring", followed immediately by the statement "contains vanillin, an artificial flavor (or flavoring)". The blank in the name is filled in with the whole number (disregarding fractions) expressing the sum of the number of units of vanilla constituent plus the number of ounces of added vanillin per gallon of the article. However, if the strength of the article is less than 2-fold, the term "_____ fold" is omitted from the name.

§ 169.182 Vanilla-vanillin powder.

(a) Vanilla-vanillin powder conforms to the definition and standard of identity and is subject to any requirement for label statement of optional ingredients prescribed for vanilla powder by § 169.179, except that for each unit of vanilla constituent as defined in § 169.3(c) contained therein, the article also contains not more than 1 ounce of added vanillin.

(b) The specified name of the food is "Vanilla-vanillin powder _____ fold" or "_____ fold vanilla-vanillin powder", followed immediately by the statement "contains vanillin, an artificial flavor (or flavoring)". If sugar is the optional blending ingredient used, the word "sugar" may replace the word "powder" in the name. The blank in the name is filled in with the whole number (disregarding fractions) expressing the sum of the number of units of vanilla constituent plus the number of ounces of added vanillin per 8 pounds of the article. However, if the strength of the article is less than 2-fold the term "_____ fold" is omitted from the name.

PART 170—FOOD ADDITIVES

Subpart A—General Provisions

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170.6 Opinion letters on food additive status.
170.10 Food additives in standardized foods.
170.15 Adoption of regulation on initiative of Commissioner.
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170.18 Tolerances for related food additives.
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Subpart B—Food Additive Safety

170.20 General principles for evaluating the safety of food additives.
170.22 Safety factors to be considered.
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170.45 Fluorine-containing compounds.
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170.60 Nitrites and/or nitrates in curing premixes.

AUTHORITY: Secs. 409, 701, 52 Stat. 1055–1056 as amended, 72 Stat. 1785–1788 as amended (21 U.S.C. 348, 371), unless otherwise noted.

Subpart A—General Provisions

§ 170.3 Definitions.

For the purposes of this subchapter, the following definitions apply:

(a) "Secretary" means the Secretary of Health, Education, and Welfare.

(b) "Department" means the Department of Health, Education, and Welfare.

(c) "Commissioner" means the Commissioner of Food and Drugs.

(d) As used in this part, the term "act" means the Federal Food, Drug, and Cosmetic Act approved June 25, 1936, 52 Stat. 1040 et seq., as amended (21 U.S.C. 301–392).

(e) "Food additives" includes all substances not exempted by section 201(s) of the act, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food. A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container. "Affecting the characteristics of food" does not include such physical effects, as protecting contents of packages, preserving shape, and preventing moisture loss. If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive. A substance that does not become a component of food, but that is used, for example, in preparing an ingredient of the food to give a different flavor, texture, or other characteristic in the food, may be a food additive.

(f) "Common use in food" means a substantial history of consumption of a substance by a significant number of consumers in the United States.

(g) The word "substance" in the definition of the term "food additive" includes a food or food component consisting of one or more ingredients.

(h) "Scientific procedures" include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance.

(i) "Safe" or "safety" means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance. Safety may be determined by scientific procedures or by general recognition of safety. In determining safety, the following factors shall be considered:

(1) The probable consumption of the substance and of any substance formed in or on food because of its use.

(2) The cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet.

(3) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as appropriate.

(j) The term "nonperishable processed food" means any processed food not subject to rapid decay or deterioration that would render it unfit for consumption. Examples are flour, sugar, cereals, packaged cookies, and crackers. Not included are hermetically sealed foods or manufactured dairy products and other processed foods requiring refrigeration.

(k) "General recognition of safety" shall be determined in accordance with § 170.30.

(l) "Prior sanction" means an explicit approval granted with respect to use of a substance in food prior to September 6, 1958, by the Food and Drug Administration or the United States Department of Agriculture pursuant to the Federal Food, Drug, and Cosmetic Act, the Poultry Products Inspection Act, or the Meat Inspection Act.

(m) "Food" includes human food, substances migrating to food from food-contact articles, pet food, and animal feed.

(n) The following general food categories are established to group specific related foods together for the purpose of establishing tolerances or limitations for the use of direct human food ingredients. Individual food products will be included within these categories according to the detailed classification lists contained in Exhibit 33B of the report of the National Academy of Sciences/National Research Council report, "A Comprehensive Survey of Industry on the Use of Food Chemicals Generally Recognized as Safe" (September 1972): [10]

(1) Baked goods and baking mixes, including all ready-to-eat and ready-to-bake products, flours, and mixes requiring preparation before serving.

(2) Beverages, alcoholic, including malt beverages, wines, distilled liquors, and cocktail mix.

(3) Beverages and beverage bases, nonalcoholic, including only special or spiced teas, soft drinks, coffee substitutes, and fruit and vegetable flavored gelatin drinks.

(4) Breakfast cereals, including ready-to-eat and instant and regular hot cereals.

(5) Cheeses, including curd and whey cheeses, cream, natural, grating, processed, spread, dip, and miscellaneous cheeses.

(6) Chewing gum, including all forms.

(7) Coffee and tea, including regular, decaffeinated, and instant types.

(8) Condiments and relishes, including plain seasoning sauces and spreads, olives, pickles, and relishes, but not spices or herbs.

(9) Confections and frostings, including candy and flavored frostings, marshmallows, baking chocolate, and brown, lump, rock, maple, powdered, and raw sugars.

(10) Dairy product analogs, including nondairy milk, frozen or liquid creamers, coffee whiteners, toppings, and other nondairy products.

(11) Egg products, including liquid, frozen, or dried eggs, and egg dishes made therefrom, i.e., egg roll, egg foo young, egg salad, and frozen multicourse egg meals, but not fresh eggs.

(12) Fats and oils, including margarine, dressings for salads, butter, salad oils, shortenings and cooking oils.

(13) Fish products, including all prepared main dishes, salads, appetizers, frozen multicourse meals, and spreads containing fish, shellfish, and other aquatic animals, but not fresh fish.

(14) Fresh eggs, including cooked eggs and egg dishes made only from fresh shell eggs.

(15) Fresh fish, including only fresh and frozen fish, shellfish, and other aquatic animals.

(16) Fresh fruits and fruit juices, including only raw fruits, citrus, melons, and berries, and home-prepared "-ades" and punches made therefrom.

(17) Fresh meats, including only fresh or home-frozen beef or veal, pork, lamb or mutton and home-prepared fresh meat-containing dishes, salads, appetizers, or sandwich spreads made therefrom.

(18) Fresh poultry, including only fresh or home-frozen poultry and game birds and home-prepared fresh poultry-containing dishes, salads, appetizers, or sandwich spreads made therefrom.

(19) Fresh vegetables, tomatoes, and potatoes, including only fresh and home-prepared vegetables.

(20) Frozen dairy desserts and mixes, including ice cream, ice milks, sherbets, and other frozen dairy desserts and specialties.

(21) Fruit and water ices, including all frozen fruit and water ices.

(22) Gelatins, puddings, and fillings, including flavored gelatin desserts, puddings, custards, parfaits, pie fillings, and gelatin base salads.

(23) Grain products and pastas, including macaroni and noodle products, rice dishes, and frozen multicourse meals, without meat or vegetables.

(24) Gravies and sauces, including all meat sauces and gravies, and tomato, milk, buttery, and specialty sauces.

(25) Hard candy and cough drops, including all hard type candies.

(26) Herbs, seeds, spices, seasonings, blends, extracts, and flavorings, including all natural and artificial spices, blends, and flavors.

(27) Jams and jellies, home-prepared, including only home-prepared jams, jellies, fruit butters, preserves, and sweet spreads.

(28) Jams and jellies, commercial, including only commercially processed jams, jellies, fruit butters, preserves, and sweet spreads.

(29) Meat products, including all meats and meat containing dishes, salads, appetizers, frozen multicourse meat meals, and sandwich ingredients prepared by commercial processing or using commercially processed meats with home preparation.

(30) Milk, whole and skim, including only whole, lowfat, and skim fluid milks.

(31) Milk products, including flavored milks and milk drinks, dry milks, toppings, snack dips, spreads, weight control milk beverages, and other milk origin products.

(32) Nuts and nut products, including whole or shelled tree nuts, peanuts, coconut, and nut and peanut spreads.

(33) Plant protein products, including the National Academy of Sciences/National Research Council "reconstituted vegetable protein" category, and meat, poultry, and fish substitutes, analogs, and extender products made from plant proteins.

(34) Poultry products, including all poultry and poultry-containing dishes, salads, appetizers, frozen multicourse poultry meals, and sandwich ingredients prepared by commercial processing or using commercially processed poultry with home preparation.

(35) Processed fruits and fruit juices, including all commercially processed fruits, citrus, berries, and mixtures; salads, juices and juice punches, concentrates, dilutions, "-ades", and drink substitutes made therefrom.

(36) Processed vegetables and vegetable juices, including all commercially processed vegetables, vegetable dishes, frozen multicourse vegetable meals, and vegetable juices and blends.

(37) Snack foods, including chips, pretzels, and other novelty snacks.

(38) Soft candy, including candy bars, chocolates, fudge, mints, and other chewy or nougat candies.

(39) Soups, home-prepared, including meat, fish, poultry, vegetable, and combination home-prepared soups.

(40) Soups and soup mixes, including commercially prepared meat, fish, poultry, vegetable, and combination soups and soup mixes.

(41) Sugar, white, granulated, including only white granulated sugar.

(42) Sugar substitutes, including granulated, liquid, and tablet sugar substitutes.

(43) Sweet sauces, toppings, and syrups, including chocolate, berry, fruit, corn syrup, and maple sweet sauces and toppings.

(o) The following terms describe the physical or technical functional effects for which direct human food ingredients may be added to foods. They are adopted from the National Academy of Sciences/National Research Council national survey of food industries, reported to the Food and Drug Administration under the contract title "A Comprehensive Survey of Industry on the Use of Food Chemicals Generally Recognized as Safe" (September 1972): [10]

(1) "Anticaking agents and free-flow agents": Substances added to finely pow-

[10] Copies may be obtained from: National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22151.

dered or crystalline food products to prevent caking, lumping, or agglomeration.

(2) "Antimicrobial agents": Substances used to preserve food by preventing growth of microorganisms and subsequent spoilage, including fungistats, mold and rope inhibitors, and the effects listed by the National Academy of Sciences/National Research Council under "preservatives."

(3) "Antioxidants": Substances used to preserve food by retarding deterioration, rancidity, or discoloration due to oxidation.

(4) "Colors and coloring adjuncts": Substances used to impart, preserve, or enhance the color or shading of a food, including color stabilizers, color fixatives, color-retention agents, etc.

(5) "Curing and pickling agents": Substances imparting a unique flavor and/or color to a food, usually producing an increase in shelf life stability.

(6) "Dough strengtheners": Substances used to modify starch and gluten, thereby producing a more stable dough, including the applicable effects listed by the National Academy of Sciences/National Research Council under "dough conditioner."

(7) "Drying agents": Substances with moisture-absorbing ability, used to maintain an environment of low moisture.

(8) "Emulsifiers and emulsifier salts": Substances which modify surface tension in the component phase of an emulsion to establish a uniform dispersion or emulsion.

(9) "Enzymes": Enzymes used to improve food processing and the quality of the finished food.

(10) "Firming agents": Substances added to precipitate residual pectin, thus strengthening the supporting tissue and preventing its collapse during processing.

(11) "Flavor enhancers": Substances added to supplement, enhance, or modify the original taste and/or aroma of a food, without imparting a characteristic taste or aroma of its own.

(12) "Flavoring agents and adjuvants": Substances added to impart or help impart a taste or aroma in food.

(13) "Flour treating agents": Substances added to milled flour, at the mill, to improve its color and/or baking qualities, including bleaching and maturing agents.

(14) "Formulation aids": Substances used to promote or produce a desired physical state or texture in food, including carriers, binders, fillers, plasticizers, film-formers, and tableting aids, etc.

(15) "Fumigants": Volatile substances used for controlling insects or pests.

(16) "Humectants": Hygroscopic substances incorporated in food to promote retention of moisture, including moisture-retention agents and antidusting agents.

(17) "Leavening agents": Substances used to produce or stimulate production of carbon dioxide in baked goods to impart a light texture, including yeast, yeast foods, and calcium salts listed by the National Academy of Sciences/National Research Council under "dough conditioners."

(18) "Lubricants and release agents": Substances added to food contact surfaces to prevent ingredients and finished products from sticking to them.

(19) "Non-nutritive sweeteners": Substances having less than 2 percent of the caloric value of sucrose per equivalent unit of sweetening capacity.

(20) "Nutrient supplements": Substances which are necessary for the body's nutritional and metabolic processes.

(21) "Nutritive sweeteners": Substances having greater than 2 percent of the caloric value of sucrose per equivalent unit of sweetening capacity.

(22) "Oxidizing and reducing agents": Substances which chemically oxidize or reduce another food ingredient, thereby producing a more stable product, including the applicable effect listed by the National Academy of Sciences/National Research Council under "dough conditioners."

(23) "pH control agents": Substances added to change or maintain active acidity or basicity, including buffers, acids, alkalies, and neutralizing agents.

(24) "Processing aids": Substances used as manufacturing aids to enhance the appeal or utility of a food or food component, including clarifying agents, clouding agents, catalysts, flocculents, filters aids, and crystallization inhibitors, etc.

(25) "Propellants, aerating agents, and gases": Gases used to supply force to expel a product or used to reduce the amount of oxygen in contact with the food in packaging.

(26) "Sequestrants": Substances which combine with polyvalent metal ions to form a soluble metal complex, to improve the quality and stability of products.

(27) "Solvents and vehicles": Substances used to extract or dissolve another substance.

(28) "Stabilizers and thickeners": Substances used to produce viscous solutions or dispersions, to impart body, improve consistency, or stabilize emulsions, including suspending and bodying agents, setting agents, jellying agents, and bulking agents, etc.

(29) "Surface-active agents": Substances used to modify surface properties of liquid food components for a variety of effects, other than emulsifiers, but including solubilizing agents, dispersants, detergents, wetting agents, rehydration enhancers, whipping agents, foaming agents, and defoaming agents, etc.

(30) "Surface-finishing agents": Substances used to increase palatability, preserve gloss, and inhibit discoloration of foods, including glazes, polishes, waxes, and protective coatings.

(31) "Synergists": Substances used to act or react with another food ingredient to produce a total effect different or greater than the sum of the effects produced by the individual ingredients.

(32) "Texturizers": Substances which affect the appearance or feel of the food.

§ 170.6 Opinion letters on food additive status.

(a) Over the years the Food and Drug Administration has given informal written opinions to inquiries as to the safety of articles intended for use as components of, or in contact with, food. Prior to the enactment of the Food Additives Amendment of 1958 (Public Law 85-929; Sept. 6, 1958), these opinions were given pursuant to section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act, which reads in part: "A food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health;".

(b) Since enactment of the Food Additives Amendment, the Food and Drug Administration has advised such inquirers that an article:

(1) Is a food additive within the meaning of section 201(s) of the act; or

(2) Is generally recognized as safe (GRAS); or

(3) Has prior sanction or approval under that amendment; or

(4) Is not a food additive under the conditions of intended use.

(c) In the interest of the public health, such articles which have been considered in the past by the Food and Drug Administration to be safe under the provisions of section 402(a)(1), or to be generally recognized as safe for their intended use, or to have prior sanction or approval, or not to be food additives under the conditions of intended use, must be reexamined in the light of current scientific information and current principles for evaluating the safety of food additives if their use is to be continued.

(d) Because of the time span involved, copies of many of the letters in which the Food and Drug Administration has expressed an informal opinion concerning the status of such articles may no longer be in the file of the Food and Drug Administration. In the absence of information concerning the names and uses made of all the articles referred to in such letters, their safety of use cannot be reexamined. For this reason all food additive status opinions of the kind described in paragraph (c) of this section given by the Food and Drug Administration are hereby revoked.

(e) The prior opinions of the kind described in paragraph (c) of this section will be replaced by qualified and current opinions if the recipient of each such letter forwards a copy of each to the Department of Health, Education, and Welfare, Food and Drug Administration, Bureau of Foods, Pesticides, and Product Safety, Office of Compliance, 200 C Street SW., Washington, DC 20204, along with a copy of his letter of inquiry, on or before July 23, 1970.

(f) This section does not apply to food additive status opinion letters pertaining to articles that were considered by the Food and Drug Administration to be food additives nor to articles included in reg-

ulations in Parts 170 through 189 of this chapter if the articles are used in accordance with the requirements of such regulations.

(Sec. 201, 72 Stat. 1784–88, as amended; 21 U.S.C. 321)

§ 170.10 Food additives in standardized foods.

(a) The inclusion of food ingredients in Parts 170 through 189 of this chapter does not imply that these ingredients may be used in standardized foods unless they are recognized as optional ingredients in applicable food standards. Where a petition is received for the issuance or amendment of a regulation establishing a definition and standard of identity for a food under section 401 of the act, which proposes the inclusion of a food additive in such definition and standard of identity, the provisions of the regulations in this part shall apply with respect to the information that must be submitted with respect to the food additive. Since section 409(b)(5) of the act requires that the Secretary publish notice of a petition for the establishment of a food-additive regulation within 30 days after filing, notice of a petition relating to a definition and standard of identity shall also be published within that time limitation if it includes a request, so designated, for the establishment of a regulation pertaining to a food additive.

(b) If a petition for a definition and standard of identity contains a proposal for a food-additive regulation, and the petitioner fails to designate it as such, the Commissioner, upon determining that the petition includes a proposal for a food-additive regulation, shall so notify the petitioner and shall thereafter proceed in accordance with the regulations in this part.

(c) A regulation will not be issued allowing the use of a food additive in a food for which a definition and standard of identity is established, unless its issuance is in conformity with section 401 of the act or with the terms of a temporary permit issued under § 130.17 of this chapter. When the contemplated use of such additive complies with the terms of a temporary permit, the food additive regulation will be conditioned on such compliance and will expire with the expiration of the temporary permit.

§ 170.15 Adoption of regulation on initiative of Commissioner.

(a) The Commissioner upon his own initiative may propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used. Notice of such proposal shall be published in the FEDERAL REGISTER and shall state the reasons for the proposal.

(b) Action upon a proposal made by the Commissioner shall proceed as provided in Part 2 of this chapter.

§ 170.17 Exemption for investigational use and procedure for obtaining authorization to market edible products from experimental animals.

A food additive or food containing a food additive intended for investigational use by qualified experts shall be exempt from the requirements of section 409 of the act under the following conditions:

(a) If intended for investigational use in vitro or in laboratory research animals, it bears a label which states prominently, in addition to the other information required by the act, the warning:

Caution. Contains a new food additive for investigational use only in laboratory research animals or for tests in vitro. Not for use in humans.

(b) If intended for use in animals other than laboratory research animals and if the edible products of the animals are to be marketed as food, permission for the marketing of the edible products as food has been requested by the sponsor, and authorization has been granted by the Food and Drug Administration in accordance with § 511.1 of this chapter or by the Department of Agriculture in accordance with § 309.17 of Title 9 (9 CFR 309.17), and it bears a label which states prominently, in addition to the other information required by the act, the warning:

Caution. Contains a new food additive for use only in investigational animals. Not for use in humans.

Edible products of investigational animals are not to be used for food unless authorization has been granted by the U.S. Food and Drug Administration or by the U.S. Department of Agriculture.

§ 170.18 Tolerances for related food additives.

(a) Food additives that cause similar or related pharmacological effects will be regarded as a class, and in the absence of evidence to the contrary, as having additive toxic effects and will be considered as related food additives.

(b) Tolerances established for such related food additives may limit the amount of a common component that may be present, or may limit the amount of biological activity (such as cholinesterase inhibition) that may be present or may limit the total amount of related food additives that may be present.

(c) Where food additives from two or more chemicals in the same class are present in or on a food, the tolerance for the total of such additives shall be the same as that for the additive having the lowest numerical tolerance in this class, unless there are available methods that permit quantitative determination of the amount of each food additive present or unless it is shown that a higher tolerance is reasonably required for the combined additives to accomplish the physical or technical effect for which such combined additives are intended and that the higher tolerance will be safe.

(d) Where residues from two or more additives in the same class are present in or on a food and there are available methods that permit quantitative determination of each residue, the quantity of combined residues that are within the tolerance may be determined as follows:

(1) Determine the quantity of each residue present.

(2) Divide the quantity of each residue by the tolerance that would apply if it occurred alone, and multiply by 100 to determine the percentage of the permitted amount of residue present.

(3) Add the percentages so obtained for all residues present.

(4) The sum of the percentage shall not exceed 100 percent.

§ 170.19 Pesticide chemicals in processed foods.

When pesticide chemical residues occur in processed foods due to the use of raw agricultural commodities that bore or contained a pesticide chemical in conformity with an exemption granted or a tolerance prescribed under section 408 of the act, the processed food will not be regarded as adulterated so long as good manufacturing practice has been followed in removing any residue from the raw agricultural commodity in the processing (such as by peeling or washing) and so long as the concentration of the residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity. But when the concentration of residue in the processed food when ready to eat is higher than the tolerance prescribed for the raw agricultural commodity, the processed food is adulterated unless the higher concentration is permitted by a tolerance obtained under section 409 of the act. For example, if fruit bearing a residue of 7 parts per million of DDT permitted on the raw agricultural commodity is dried and a residue in excess of 7 parts per million of DDT results on the dried fruit, the dehydrated fruit is adulterated unless the higher tolerance for DDT is authorized by the regulations in this part. Food that is itself ready to eat, and which contains a higher residue than allowed for the raw agricultural commodity, may not be legalized by blending or mixing with other foods to reduce the residue in the mixed food below the tolerance prescribed for the raw agricultural commodity.

Subpart B—Food Additive Safety

§ 170.20 General principles for evaluating the safety of food additives.

(a) In reaching a decision on any petition filed under section 409 of the act, the Commissioner will give full consideration to the specific biological properties of the compound and the adequacy of the methods employed to demonstrate safety for the proposed use, and the Commissioner will be guided by the principles and procedures for establishing the safety of food additives stated in current publications of the National Academy of Sciences-National Research Council. A petition will not be denied, however, by reason of the petitioner's having followed procedures other than those outlined in the publications of the National Academy of Sciences-National Research Council if, from available evidence, the Commissioner finds that the procedures used give results as reliable as, or more reliable than, those reasonably to be expected from the use of the outlined procedures. In reaching a decision, the Commissioner will give due weight to the anticipated levels and patterns of consumption of the additive specified or reasonably inferrable. For the purposes of

this section, the principles for evaluating safety of additives set forth in the abovementioned publications will apply to any substance that may properly be classified as a food additive as defined in section 201(s) of the act.

(b) Upon written request describing the proposed use of an additive and the proposed experiments to determine its safety, the Commissioner will advise a person who wishes to establish the safety of a food additive whether he believes the experiments planned will yield data adequate for an evaluation of the safety of the additive.

§ 170.22 Safety factors to be considered.

In accordance with section 409(c)(5)(C) of the act, the following safety factors will be applied in determining whether the proposed use of a food additive will be safe: Except where evidence is submitted which justifies use of a different safety factor, a safety factor in applying animal experimentation data to man of 100 to 1, will be used; that is, a food additive for use by man will not be granted a tolerance that will exceed 1/100th of the maximum amount demonstrated to be without harm to experimental animals.

§ 170.30 Eligibility for classification as generally recognized as safe (GRAS).

(a) General recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.

(b) General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information.

(c) General recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive regulation. General recognition of safety through experience based on common use in food prior to January 1, 1958, shall ordinarily be based upoh generally available data and information. An ingredient not in common use in food prior to January 1, 1958, may achieve general recognition of safety only through scientific procedures.

(d) The food ingredients listed as GRAS in Part 182 of this chapter or affirmed as GRAS in Part 184 or § 186.1 of this chapter do not include all substances that are generally recognized as safe for their intended use in food. Because of the large number of substances the intended use of which results or may reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of food, it is impracticable to list all such substances that are GRAS. A food ingredient of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effects, which is subject only to conventional processing as practiced prior to January 1, 1958, and for which no known safety hazard exists, will ordinarily be regarded as GRAS without specific inclusion in Part 182, Part 184 or § 186.1 of this chapter.

(e) Food ingredients were listed as GRAS in Part 182 of this chapter during 1958–1962 without a detailed scientific review of all available data and information relating to their safety. Beginning in 1969, the Food and Drug Administration has undertaken a systematic review of the status of all ingredients used in food on the determination that they are GRAS or subject to a prior sanction. All determinations of GRAS status or food additive status or prior sanction status pursuant to this review shall be handled pursuant to §§ 170.35, 170.38, and 180.1 of this chapter. Affirmation of GRAS status shall be announced in Part 184 or § 186.1 of this chapter.

(f) The status of the following food ingredients will be reviewed and affirmed as GRAS or determined to be a food additive or subject to a prior sanction pursuant to § 170.35, § 170.38, or § 180.1 of this chapter:

(1) Any substance of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effect, for which no health hazard is known, and which has been modified by processes first introduced into commercial use after January 1, 1958, which may reasonably be expected significantly to alter the composition of the substance.

(2) Any substance of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effect, for which no health hazard is known, that has had significant alteration of composition by breeding or selection after January 1, 1958, where the change may be reasonably expected to alter the nutritive value or the concentration of toxic constituents.

(3) Distillates, isolates, extracts, and concentration of extracts of GRAS substances.

(4) Reaction products of GRAS substances.

(5) Substances not of a natural biological origin, including those for which evidence is offered that they are identical to a GRAS counterpart of natural biological origin.

(6) Substances of natural biological origin intended for consumption for other than their nutrient properties.

(g) A food ingredient that is not GRAS or subject to a prior sanction requires a food additive regulation promulgated under section 409 of the act before it may be directly or indirectly added to food.

(h) A food ingredient that is listed as GRAS in Part 182 of this chapter or affirmed as GRAS in Part 184 or § 186.1 of this chapter shall be regarded as GRAS only if, in addition to all the requirements in the applicable regulation, it also meets all of the following requirements:

(1) It complies with any applicable food grade specifications of the Food Chemicals Codex, 2d Ed. (1972) [1]; except that any substance used as a component of articles that contact food and affirmed as GRAS in § 186.1 of this chapter shall comply with the specifications therein, or in the absence of such specifications, shall be of a purity suitable for its intended use.

(2) It performs an appropriate function in the food or food-contact article in which it is used.

(3) It is used at a level no higher than necessary to achieve its intended purpose in that food or, if used as a component of a food-contact article, at a level no higher than necessary to achieve its intended purpose in that article.

(i) If a substance is affirmed as GRAS in Part 184 or § 186.1 of this chapter with no limitation other than good manufacturing practice, it shall be regarded as GRAS if its conditions of use are not significantly different from those reported in the regulation as the basis on which the GRAS status of the substance was affirmed. If the conditions of use are significantly different, such use of the substance may not be GRAS. In such a case a manufacturer may not rely on the regulation as authorizing the use but must independently establish that the use is GRAS or must use the substance in accordance with a food additive regulation.

(j) If an ingredient is affirmed as GRAS in Part 184 or § 186.1 of this chapter with specific limitation(s), it may be used in food only within such limitation(s) (including the category of food(s), the functional use(s) of the ingredient, and the level(s) of use). Any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation.

(k) Pursuant to § 170.35, a food ingredient may be affirmed as GRAS in Part 184 or § 186.1 of this chapter for a specific use(s) without a general evaluation of use of the ingredient. In addition to the use(s) specified in the regulation, other uses of such an ingredient may also be GRAS. Any affirmation of GRAS status for a specific use(s), without a general evaluation of use of the ingredient, is subject to reconsideration upon such evaluation.

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[1] Copies may be obtained from: The National Academy of Sciences, 2101 Constitution Ave. NW., Washington, D.C. 20037.

(1) New information may at any time require reconsideration of the GRAS status of a food ingredient. Any change in Part 182, Part 184, or § 186.1 of this chapter shall be accomplished pursuant to § 170.38.

§ 170.35 Affirmation of generally recognized as safe (GRAS) status.

(a) The Commissioner, either on his initiative or on the petition of an interested person, may affirm the GRAS status of substances that directly or indirectly become components of food.

(b) (1) If the Commissioner proposes on his own initiative that a substance is entitled to affirmation as GRAS, he will place all of the data and information on which he relies on public file in the office of the Hearing Clerk and will publish in the FEDERAL REGISTER a notice giving the name of the substance, its proposed uses, and any limitations proposed for purposes other than safety.

(2) The FEDERAL REGISTER notice will allow a period of 60 days during which any interested person may review the data and information and/or file comments with the Hearing Clerk. Copies of all comments received shall be made available for examination in the Hearing Clerk's office.

(3) The Commissioner will evaluate all comments received. If he concludes that there is convincing evidence that the substance is GRAS as described in § 170.30, he will publish a notice in the FEDERAL REGISTER listing the substance as GRAS in Part 182, Part 184, or Part 186 of this chapter, as appropriate.

(4) If, after evaluation of the comments, the Commissioner concludes that there is a lack of convincing evidence that the substance is GRAS and that it should be considered a food additive subject to section 409 of the act, he shall publish a notice thereof in the FEDERAL REGISTER in accordance with § 170.38.

(c) (1) Persons seeking the affirmation of GRAS status of substances as provided for in § 170.30(e), except those subject to the NAS–NRC GRAS list survey (36 FR 20546), shall submit a petition for GRAS affirmation pursuant to Part 2 of this chapter. Such petition shall contain information to establish that the GRAS criteria as set forth in § 170.30(b) have been met, in the following form:

(i) Description of the substance, including:

(*a*) Common or usual name.

(*b*) Chemical name.

(*c*) Chemical Abstract Service (CAS) registry number.

(*d*) Empirical formula.

(*e*) Structural formula.

(*f*) Specifications for food grade material, including arsenic and heavy metals. (Recommendation for any change in the Food Chemicals Codex monograph should be included where applicable.)

(*g*) Quantitative compositions.

(*h*) Manufacturing process (excluding any trade secrets).

(ii) Use of the substance, including:

(*a*) Date when use began.

(*b*) Information and reports or other data on past uses in food.

(*c*) Foods in which used, and levels of use in such foods, and for what purposes.

(iii) Methods for detecting the substance in food, including:

(*a*) References to qualitative and quantitative methods for determining the substance(s) in food, including the type of analytical procedures used.

(*b*) Sensitivity and reproducibility of such method(s).

(iv) Information to establish the safety and functionality of the substance in food. Published scientific literature, evidence that the substance is identical to a GRAS counterpart of natural biological origin, and other data may be submitted to support safety. Any adverse information or consumer complaints shall be included. Complete bibliographic references shall be provided where a copy of the article is not provided.

(v) A statement signed by the person responsible for the petition that to the best of his knowledge it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him pertinent to the evaluation of the safety and functionality of the substance.

(2) Within 30 days after the date of filing the petition, the Commissioner will place the petition on public file in the office of the Hearing Clerk and will publish a notice of filing in the FEDERAL REGISTER giving the name of the petitioner and a brief description of the petition including the name of the substance, its proposed use, and any limitations proposed for reasons other than safety. A copy of the notice will be mailed to the petitioner at the time the original is sent to the FEDERAL REGISTER.

(3) The notice of filing in the FEDERAL REGISTER will allow a period of 60 days during which any interested person may review the petition and/or file comments with the Hearing Clerk. Copies of all comments received shall be made available for examination in the Hearing Clerk's office.

(4) The Commissioner will evaluate the petition and all available information including all comments received. If the petition and such information provide convincing evidence that the substance is GRAS as described in § 170.30 he will publish an order in the FEDERAL REGISTER listing the substance as GRAS in Part 182, Part 184, or Part 186 of this chapter, as appropriate.

(5) If, after evaluation of the petition and all available information, the Commissioner concludes that there is a lack of convincing evidence that the substance is GRAS and that it should be considered a food additive subject to section 409 of the act, he shall publish a notice thereof in the FEDERAL REGISTER in accordance with § 170.38.

(6) The notice of filing in the FEDERAL REGISTER will request submission of proof of any applicable prior sanction for use of the ingredient under conditions different from those proposed to be determined to be GRAS. The failure of any person to come forward with proof of such an applicable prior sanction in response to the notice of filing will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice of filing will also constitute a proposal to establish a regulation under Part 181 of this chapter, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the notice of filing.

(Sec. 201, 72 Stat. 1784–1788; 21 U.S.C. 321)

§ 170.38 Determination of food additive status.

(a) The Commissioner may, in accordance with § 170.35 (b) (4) or (c) (5), publish a notice in the FEDERAL REGISTER determining that a substance is not GRAS and is a food additive subject to section 409 of the act.

(b) (1) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to Part 2 of this chapter, may issue a notice in the FEDERAL REGISTER proposing to determine that a substance is not GRAS and is a food additive subject to section 409 of the act. Any petition shall include all relevant data and information of the type described in § 171.130(b). The Commissioner will place all of the data and information on which he relies on public file in the office of the Hearing Clerk and will include in the FEDERAL REGISTER notice the name of the substance, its known uses, and a summary of the basis for the determination.

(2) The FEDERAL REGISTER notice will allow a period of 60 days during which any interested person may review the data and information and/or file comments with the Hearing Clerk. Copies of all comments shall be made available for examination in the Hearing Clerk's office.

(3) The Commissioner will evaluate all comments received. If he concludes that there is a lack of convincing evidence that the substance is GRAS or is otherwise exempt from the definition of a food additive in section 201(s) of the act, he will publish a notice thereof in the FEDERAL REGISTER. If he concludes that there is convincing evidence that the substance is GRAS, he will publish an order in the FEDERAL REGISTER listing the substance as GRAS in Part 182, Part 184, or Part 186 of this chapter, as appropriate.

(c) A FEDERAL REGISTER notice determining that a substance is a food additive shall provide for the use of the additive in food or food contact surfaces as follows:

(1) It may promulgate a food additive regulation governing use of the additive.

(2) It may promulgate an interim food additive regulation governing use of the additive.

(3) It may require discontinuation of the use of the additive.

(4) It may adopt any combination of the above three approaches for different uses or levels of use of the additive.

(d) If the Commissioner of Food and Drugs is aware of any prior sanction for

use of the substance, he will concurrently propose a separate regulation covering such use of the ingredient under Part 181 of this chapter. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any regulation promulgated pursuant to this section constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to the proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under Part 181 of this chapter, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

(Sec. 201, 72 Stat. 1784–1788; 21 U.S.C. 321)

Subpart C—Specific Administrative Rulings and Decisions

§ 170.45 Fluorine-containing compounds.

The Commissioner of Food and Drugs has concluded that it is in the interest of the public health to limit the addition of fluorine compounds to foods (a) to that resulting from the fluoridation of public water supplies as stated in § 250.-203 of this chapter, (b) to that resulting from the fluoridation of bottled water within the limitation established in § 103.35(d) of this chapter, and (c) to that authorized by regulations (40 CFR Part 180) under section 408 of the act.

§ 170.50 Glycine (aminoacetic acid) in food for human consumption.

(a) Heretofore, the Food and Drug Administration has expressed the opinion in trade correspondence that glycine is generally recognized as safe for certain technical effects in human food when used in accordance with good manufacturing practice; however:

(1) Reports in scientific literature indicate that adverse effects were found in cases where high levels of glycine were administered in diets of experimental animals.

(2) Current usage information indicates that the daily dietary intake of glycine by humans may be substantially increasing due to changing use patterns in food technology.

Therefore, the Food and Drug Administration no longer regards glycine and its salts as generally recognized as safe for use in human food and all outstanding letters expressing sanction for such use are rescinded.

(b) The Commissioner of Food and Drugs concludes that by May 8, 1971, manufacturers:

(1) Shall reformulate food products for human use to eliminate added glycine and its salts; or

(2) Shall bring such products into compliance with an authorizing food additive regulation. A food additive petition supported by toxicity data is required to show that any proposed level of glycine or its salts added to foods for human consumption will be safe.

(c) The status of glycine as generally recognized as safe for use in animal feed, as prescribed in § 582.5049 of this chapter, remains unchanged because the additive is considered an essential nutrient in certain animal feeds and is safe for such use under conditions of good feeding practice.

(Sec. 201(s), 72 Stat. 1784–88, as amended; 21 U.S.C. 321(s).)

§ 170.60 Nitrites and/or nitrates in curing premixes.

(a) Nitrites and/or nitrates are food additives when combined in curing premixes with spices and/or other flavoring or seasoning ingredients that contain or constitute a source of secondary or tertiary amines, including but not limited to essential oils, disodium inosinate, disodium guanylate, hydrolysates of animal or plant origin (such as hydrolyzed vegetable protein), oleoresins of spices, soy products, and spice extractives. Such food additives may be used only after the establishment of an authorizing food additive regulation. A food additive petition submitted pursuant to §§ 171.1 and 171.100 of this chapter, supported by data demonstrating that nitrosamines are not formed in curing premixes containing such food additives, is required to establish safety.

(b) Nitrites and/or nitrates, when packaged separately from flavoring and seasoning in curing premixes, may continue to be used under prior sanctions in the commercial curing of meat and meat products and poultry products and in accordance with the provisions of §§ 172.-170 and 172.175 of this chapter that apply to meat curing preparations for the home curing of meat and meat products, including poultry and wild game. To assure safe use of such ingredients the labeling of the premixes shall bear instructions to the user that such separately packaged ingredients are not to be combined until just prior to use. Encapsulating or coating some or all of the ingredients does not constitute separate packaging.

PART 171—FOOD ADDITIVE PETITIONS

Subpart A—General Provisions

Sec.
171.1 Petitions.
171.6 Amendment of petition.
171.7 Withdrawal of petition without prejudice.

Subpart B—Administrative Actions on Applications

171.100 Regulation based on petition.
171.102 Effective date of regulation.
171.110 Objection to regulation and request for hearing.
171.130 Procedure for amending and repealing tolerances or exemptions from tolerances.

AUTHORITY: Secs. 409, 701, 52 Stat. 1055–1056 as amended, 72 Stat. 1785–1788 as amended (21 U.S.C. 348, 371), unless otherwise noted.

Subpart A—General Provisions

§ 171.1 Petitions.

(a) Petitions to be filed with the Commissioner under the provisions of section 409(b) of the act shall be submitted in triplicate. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state petitioner's post office address to which published notices or orders issued or objections filed pursuant to section 409 of the act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized in a written statement signed by the person who submitted it. Any reference to published information offered in support of a food-additive petition should be accompanied by reprints or photostatic copies of such references.

(c) Petitions shall include the following data and be submitted in the following form:

(Date)

Name of petitioner----------
Post-office address----------
Date ----------
Name of food additive and proposed use----

Petitions Control Branch
Food and Drug Administration
Department of Health, Education, and Welfare
Washington, D.C. 20204.

DEAR SIRS:

The undersigned, ----------
submits this petition pursuant to section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act with respect to----------
---
(Name of the food additive and proposed use)

Attached hereto, in triplicate, and constituting a part of this petition, are the following:

A. The name and all pertinent information concerning the food additive, including chemical identity and composition of the food additive, its physical, chemical, and biological properties, and specifications prescribing the minimum content of the desired component(s) and identifying and limiting the reaction byproducts and other impurities. Where such information is not available, a statement as to the reasons why it is not should be submitted.

When the chemical identity and composition of the food additive is not known, the petition shall contain information in sufficient detail to permit evaluation regarding the method of manufacture and the analytical controls used during the various stages of manufacturing, processing, or packing of the food additive which are relied upon to establish that it is a substance of reproducible composition. Alternative methods and controls and variations in methods and controls within reasonable limits that do not affect the characteristics of the substance or the reliability of the controls may be specified.

If the food additive is a mixture of chemicals, the petition shall supply a list of all substances used in the synthesis, extraction, or other method of preparation, regardless of whether they undergo chemical change in the process. Each substance should be identified by its common English name and complete chemical name, using structural formulas when necessary for specific identification. If any proprietary preparation is used as a component, the proprietary name should be followed by a complete quantitative statement of composition. Reasonable alternatives for any listed substance may be specified.

If the petitioner does not himself perform all the manufacturing, processing, and packing operations for a food additive, the petition shall identify each person who will perform a part of such operations and designate the part.

The petition shall include stability data, and, if the data indicate that it is needed to insure the identity, strength, quality, or purity of the additive, the expiration date that will be employed.

B. The amount of the food additive proposed for use and the purposes for which it is proposed, together with all directions, recommendations, and suggestions regarding the proposed use, as well as specimens of the labeling proposed for the food additive and any labeling that will be required by applicable provisions of the Federal Food, Drug, and Cosmetic Act on the finished food by reason of the use of the food additive. If the additive results or may reasonably be expected to result from the use of packaging material, the petitioner shall show how this may occur and what residues may reasonably be anticipated.

(Typewritten or other draft-labeling copy will be accepted for consideration of the petition, provided a statement is made that final printed labeling identical in content to the draft copy will be submitted as soon as available and prior to the marketing of the food additive.

If the food additive is one for which a tolerance limitation is required to assure its safety, the level of use proposed should be no higher than the amount reasonably required to accomplish the intended physical or other technical effect, even though the safety data may support a higher tolerance.)

C. Data establishing that the food additive will have the intended physical or other technical effect or that it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food and the amount necessary to accomplish this. These data should include information in sufficient detail to permit evaluation with control data.

D. A description of practicable methods to determine the amount of the food additive in the raw, processed, and/or finished food and of any substance formed in or on such food because of its use. The test proposed shall be one that can be used for food-control purposes and that can be applied with consistent results by any properly equipped and trained laboratory personnel.

E. Full reports of investigations made with respect to the safety of the food additive.

(A petition may be regarded as incomplete unless it includes full reports of adequate tests reasonably applicable to show whether or not the food additive will be safe for its intended use. The reports ordinarily should include detailed data derived from appropriate animal and other biological experiments in which the methods used and the results obtained are clearly set forth. The petition shall not omit without explanation any reports of investigations that would bias an evaluation of the safety of the food additive.)

F. Proposed tolerances for the food additive, if tolerances are required in order to insure its safety. A petitioner may include a proposed regulation.

G. If submitting petition to modify an existing regulation issued pursuant to section 409(c)(1)(A) of the act, full information on each proposed change that is to be made in the original regulation must be submitted. The petition may omit statements made in the original petition concerning which no change is proposed. A supplemental petition must be submitted for any change beyond the variations provided for in the original petition and the regulation issued on the basis of the original petition.

H. The petitioner is required to submit an environmental impact analysis report analyzing the environmental impact of the manufacturing process and the ultimate use or consumption of the food additive pursuant to § 6.1 of this chapter.

Yours very truly,

Petitioner ----------

By ----------

(Indicate authority)

(d) The petitioner will be notified of the date on which his petition is filed; and an incomplete petition, or one that has not been submitted in triplicate, will usually be retained but not filed as a petition under section 409 of the act. The petitioner will be notified in what respects his petition is incomplete.

(e) The petition must be signed by the petitioner or by his attorney or agent, or (if a corporation) by an authorized official.

(f) The data specified under the several lettered headings should be submitted on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application, the present petition may incorporate it by specific reference to the earlier. If part of the data have been submitted by the manufacturer of the food additive as a master file, the petitioner may refer to the master file if and to the extent he obtains the manufacturer's written permission to do so. The manufacturer may authorize specific reference to the data without disclosure to the petitioner. Nothing herein shall prevent reference to published data.

(g) A petition shall be retained but shall not be filed if any of the data prescribed by section 409(b) of the act are lacking or are not set forth so as to be readily understood.

(h)(1) The following data and information in a food additive petition are available for public disclosure, unless extraordinary circumstances are shown, after the notice of filing of the petition is published in the FEDERAL REGISTER or, if the petition is not promptly filed because of deficiencies in it, after the petitioner is informed that it will not be filed because of the deficiencies involved:

(i) All safety and functionality data and information submitted with or incorporated by reference in the petition.

(ii) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 4.61 of this chapter.

(iii) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(*a*) Names and any information that would identify the person using the product.

(*b*) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(iv) A list of all ingredients contained in a food additive, whether or not it is in descending order of predominance. A particular ingredient or group of ingredients shall be deleted from any such list prior to public disclosure if it is shown to fall within the exemption established in § 4.61 of this chapter, and a notation shall be made that any such ingredient list is incomplete.

(v) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 4.61 of this chapter.

(2) The following data and information in a food additive petition are not available for public disclosure unless they have been previously disclosed to the public as defined in § 4.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 4.61 of this chapter:

(i) Manufacturing methods or processes, including quality control procedures.

(ii) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(iii) Quantitative or semiquantitative formulas.

(3) All correspondence and written summaries of oral discussions relating to a food additive petition are available for public disclosure in accordance with the provisions of Part 4 of this chapter when the food additive regulation is published in the FEDERAL REGISTER.

(4) For purposes of this regulation, safety and functionality data include all studies and tests of a food additive on animals and humans and all studies and tests on a food additive for identity, stability, purity, potency, performance, and usefulness.

(i)(1) Within 15 days after receipt, the Commissioner will notify the petitioner of acceptance or nonacceptance of a petition, and if not accepted the reasons therefor. If accepted, the date of the notification letter sent to petitioner becomes the date of filing for the purposes of section 409(b)(5) of the act. If the petitioner desires, he may supplement a deficient petition after being notified regarding deficiencies. If the supplementary material or explanation of the petition is deemed acceptable, petitioner shall be notified. The date of such notification becomes the date of filing. If the petitioner does not wish to supplement

or explain the petition and requests in writing that it be filed as submitted, the petition shall be filed and the petitioner so notified. The date of such notification becomes the date of filing.

(2) The Commissioner will publish in the FEDERAL REGISTER within 30 days from the date of filing of such petition, a notice of the filing, the name of the petitioner, and a brief description of the proposal in general terms. In the case of a food additive which becomes a component of food by migration from packaging material, the notice shall include the name of the migratory substance, and where it is different from that of one of the original components, the name of the parent component, the maximum quantity of the migratory substance that is proposed for use in food, and the physical or other technical effect which the migratory substance or its parent component is intended to have in the packaging material. A copy of the notice will be mailed to the petitioner when the original is forwarded to the FEDERAL REGISTER for publication.

(j) The Commissioner may request a full description of the methods used in, and the facilities and controls used for, the production of the food additive, or a sample of the food additive, articles used as components thereof, or of the food in which the additive is proposed to be used, at any time while a petition is under consideration. The Commissioner shall specify in the request for a sample of the food additive, or articles used as components thereof, or of the food in or on which the additive is proposed to be used, a quantity deemed adequate to permit tests of analytical methods to determine quantities of the food additive present in foods for which it is intended to be used or adequate for any study or investigation reasonably required with respect to the safety of the food additive or the physical or technical effect it produces. The date used for computing the 90-day limit for the purposes of section 409(c)(2) of the act shall be moved forward 1 day for each day after the mailing date of the request taken by the petitioner to submit the sample. If the information or sample is requested a reasonable time in advance of the 180 days, but is not submitted within such 180 days after filing of the petition, the petition will be considered withdrawn without prejudice.

§ 171.6 Amendment of petition.

After a petition has been filed, the petitioner may submit additional information or data in support thereof. In such cases, if the Commissioner determines that the additional information or data amounts to a substantive amendment, the petition as amended will be given a new filing date, and the time limitation will begin to run anew. Where the substantive amendment proposes a substantial change to the petition which may affect the quality of the human environment, the petitioner is required to submit an environmental impact analysis report pursuant to § 6.1 of this chapter.

§ 171.7 Withdrawal of petition without prejudice.

(a) In some cases the Commissioner will notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a regulation or the regulation requested by petitioner. This may be due to the fact that the data are not sufficiently clear or complete. In such cases, the petitioner may withdraw the petition pending its clarification or the obtaining of additional data. This withdrawal will be without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew from the date of refiling.

(b) At any time before the order provided for in § 171.100(a) has been forwarded to the FEDERAL REGISTER for publication, the petitioner may withdraw the petition without prejudice to a future filing. Upon refiling the time limitation will begin to run anew.

Subpart B—Administrative Actions on Applications

§ 171.100 Regulation based on petition.

(a) The Commissioner will forward for publication in the FEDERAL REGISTER, within 90 days after filing of the petition (or within 180 days if the time is extended as provided for in section 409(c)(2) of the act), a regulation prescribing the conditions under which the food additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity that may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and prior to the forwarding of the order to the FEDERAL REGISTER for publication shall notify the petitioner of such order and the reasons for such action; or by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(b) If the Commissioner determines that additional time is needed to study and investigate the petition, he shall by written notice to the petitioner extend the 90-day period for not more than 180 days after the filing of the petition.

§ 171.102 Effective date of regulation.

A regulation published in accordance with § 171.100(a) shall become effective upon publication in the FEDERAL REGISTER.

§ 171.110 Procedure for objections and hearings.

Objections and hearings relating to food additive regulations under section 409 (c), (d), or (h) of the act shall be governed by Part 2 of this chapter.

§ 171.130 Procedure for amending and repealing tolerances or exemptions from tolerances.

(a) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to Part 2 of this chapter, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive.

(b) Any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data shall be furnished in the form specified in §§ 171.1 and 171.100 for submitting petitions.

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

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Sec.
172.510 Natural flavoring substances and natural substances used in conjunction with flavors.
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Subpart G—Gums, Chewing Gum Bases and Related Substances

172.610 Arabinogalactan.
172.615 Chewing gum base.
172.620 Carrageenan.
172.623 Carrageenan with polysorbate 80.
172.626 Salts of carrageenan.
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172.660 Salts of furcelleran.
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Subpart H—Other Specific Usage Additives

172.710 Adjuvants for pesticide use dilutions.
172.712 Dimethyl dialkyl ammonium chloride.
172.715 Calcium lignosulfonate.
172.720 Calcium lactobionate.
172.725 Gibberellic acid and its potassium salt.
172.730 Potassium bromate.
172.735 Glycerol ester of wood rosin.
172.755 Stearyl monoglyceridyl citrate.
172.765 Succistearin (stearoyl propylene glycol hydrogen succinate).
172.770 Ethylene oxide polymer.
172.775 Methacrylic acid-divinylbenzene copolymer.

Subpart I—Multipurpose Additives

172.802 Acetone peroxides.
172.804 Aspartame.
172.806 Azodicarbonamide.
172.808 Copolymer condensates of ethylene oxide and propylene oxide.
172.810 Dioctyl sodium sulfosuccinate.
172.812 Glycine.
172.814 Hydroxylated lecithin.
172.816 Methyl glucoside-coconut oil ester.
172.818 Oxystearin.
172.820 Polyethylene gylcol (mean molecular weight 200–9,500).
172.822 Sodium lauryl sulfate.
172.824 Sodium mono- and dimethyl naphthalene sulfonates.
172.826 Sodium stearyl fumarate.
172.828 Acetylated monoglycerides.
172.830 Succinylated monoglycerides.
172.832 Monoglyceride citrate.
172.834 Ethoxylated mono- and diglycerides.
172.836 Polysorbate 60.
172.838 Polysorbate 65.
172.840 Polysorbate 80.
172.842 Sorbitan monostearate.
172.844 Calcium stearoyl-2-lactylate.
172.846 Sodium stearoyl-2-lactylate.
172.848 Lactylic esters of fatty acids.
172.850 Lactylated fatty acid esters of glycerol and propylene glycol.
172.852 Glyceryl-lacto esters of fatty acids.
172.854 Polyglycerol esters of fatty acids.
172.856 Propylene glycol mono- and diesters of fats and fatty acids.
172.858 Propylene glycol alginate.
172.860 Fatty acids.
172.862 Oleic acid derived from tall oil fatty acids.
172.863 Salts of fatty acids.
172.864 Synthetic fatty alcohols.
172.866 Synthetic glycerin produced by the hydrogenolysis of carbohydrates.
172.868 Ethyl cellulose.
172.870 Hydroxypropyl cellulose.
172.872 Methyl ethyl cellulose.
172.874 Hydroxypropyl methylcellulose.
172.876 Castor oil.
172.878 White mineral oil.
172.880 Petrolatum.
172.882 Synthetic isoparaffinic petroleum hydrocarbons.
172.884 Odorless light petroleum hydrocarbons.
172.886 Petroleum wax.
172.888 Synthetic petroleum wax.
172.890 Rice bran wax.
172.892 Food starch-modified.
172.894 Modified cottonseed products intended for human consumption.
172.896 Dried yeasts.
172.898 Bakers yeast glycan.

AUTHORITY: Secs. 409, 701, 52 Stat. 1055–1056 as amended, 72 Stat. 1785–1788 as amended (21 U.S.C. 348, 371), unless otherwise noted.

Subpart A—General Provisions

§ 172.5 General provisions for direct food additives.

(a) Regulations prescribing conditions under which food additive substances may be safely used predicate usage under conditions of good manufacturing practice. For the purposes of this part, good manufacturing practice shall be defined to include the following restrictions.

(1) The quantity of the substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritive, or other technical effect in food.

(2) Any substance intended for use in or on food is of appropriate food grade and is prepared and handled as a food ingredient.

(b) The existence of a regulation prescribing safe conditions of use for a food additive shall not be construed to relieve the use of the substance from compliance with any other provision of the act.

(c) The existence of any regulation prescribing safe conditions of use for a nutrient substance does not constitute a finding that the substance is useful or required as a supplement to the diet of humans.

Subpart B—Food Preservatives

§ 172.110 BHA.

The food additive BHA (butylated hydroxyanisole) alone or in combination with other antioxidants permitted in food for human consumption in this Subpart B may be safely used in or on specified foods, as follows:

(a) The BHA meets the following specification:

Assay (total BHA), 98.5 percent minimum. Melting point 48° C minimum.

(b) The BHA is used alone or in combination with BHT, as an antioxidant in foods, as follows:

Food	*Limitations (total BHA and BHT) parts per million*
Dehydrated potato shreds	50
Active dry yeast	[1] 1,000
Beverages and desserts prepared from dry mixes	[1] 2
Dry breakfast cereals	50
Dry diced glazed fruit	[1] 32
Dry mixes for beverages and desserts	[1] 90
Emulsion stabilizers for shortenings	200
Potato flakes	50
Potato granules	10
Sweetpotato flakes	50

[1] BHA only.

(c) To assure safe use of the additive:

(1) The label of any market package of the additive shall bear, in addition to the other information required by the act, the name of the additive.

(2) When the additive is marketed in a suitable carrier, in addition to meeting the requirement of paragraph (c)(1) of this section, the label shall declare the percentage of the additive in the mixture.

(3) The label or labeling of dry mixes for beverages and desserts shall bear adequate directions for use to provide that beverages and desserts prepared from the dry mixes contain no more than 2 parts per million BHA.

§ 172.115 BHT.

The food additive BHT (butylated hydroxytoluene), alone or in combination with other antioxidants permitted in this Subpart B may be safely used in or on specified foods, as follows:

(a) The BHT meets the following specification: Assay (total BHT) 99 percent minimum.

(b) The BHT is used alone or in combination with BHA, as an antioxidant in foods, as follows:

Food	*Limitations (total BHA and BHT) parts per million*
Dehydrated potato shreds	50
Dry breakfast cereals	50
Emulsion stabilizers for shortenings	200
Potato flakes	50
Potato granules	10
Sweetpotato flakes	50

(c) To assure safe use of the additive:

(1) The label of any market package of the additive shall bear, in addition to the other information required by the act, the name of the additive.

(2) When the additive is marketed in a suitable carrier, in addition to meeting the requirement of paragraph (c)(1) of this section, the label shall declare the percentage of the additive in the mixture.

§ 172.120 Calcium disodium EDTA.

The food additive calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate) may be safely used in designated foods for the purposes and

in accordance with the conditions prescribed, as follows:

(a) The additive contains a minimum of 99 percent by weight of either the dihydrate $C_{10}H_{12}O_5N_2CaNa_2 \cdot 2H_2O$ or the trihydrate $C_{10}H_{12}O_5N_2CaNa_2 \cdot 3H_2O$, or any mixture of the two.

(b) It is used or intended for use as follows:

(1) Alone, in the following foods at not to exceed the levels prescribed, calculated as the anhydrous compound:

Food	Limitation (parts per million)	Use
Cabbage, pickled	220	Promote color, flavor, and texture retention.
Canned carbonated soft drinks.	33	Promote flavor retention.
Canned white potatoes.	110	Promote color retention.
Clams (cooked canned).	340	Promote color retention.
Crabmeat (cooked canned).	275	Retard struvite formation; promote color retention.
Cucumbers pickled	220	Promote color, flavor, and texture retention.
Distilled alcoholic beverages.	25	Promote stability of color, flavor, and/or product clarity.
Dressings, nonstandardized.	75	Preservative.
Dried lima beans (cooked canned).	310	Promote color retention.
Egg product that is hard-cooked and consists, in a cylindrical shape, of egg white with an inner core of egg yolk.	[1] 260	Preservative.
Fermented malt beverages.	25	Antigushing agent.
French dressing	75	Preservative.
Mayonnaise	75	Do.
Mushrooms (cooked canned).	260	Promote color retention when such use is prescribed by an effective temporary permit issued under sec. 130.17 of this chapter.
Oleomargarine	75	Preservative.
Pecan pie filling	100	Promote color retention.
Potato salad	100	Preservative.
Processed dry pinto beans.	800	Promote color retention.
Salad dressing	75	Preservative.
Sandwich spread	100	Do.
Sauces	75	Do.
Shrimp (cooked canned).	250	Retard struvite formation; promote color retention.
Spice extractives in soluble carriers.	85	Promote color and flavor retention.
Spreads, artificially colored and lemon-flavored or orange-flavored.	100	Promote color retention.

[1] By weight of egg yolk portion.

(2) With disodium EDTA (disodium ethylenediaminetetraacetate) in the following foods at not to exceed, in combination, the levels prescribed, calculated as anhydrous $C_{10}H_{12}O_8N_2CaNa_2$:

Food	Limitation (parts per million)	Use
Dressings, nonstandardized	75	Preservative.
French dressing	75	Do.
Mayonnaise	75	Do.
Salad dressing	75	Do.
Sandwich spread	100	Do.
Sauces	75	Do.

(c) To asure safe use of the additive:

(1) The label and labeling of the additive container shall bear, in addition to the other information required by the act, the name of the additive.

(2) The label or labeling of the additive container shall bear adequate use directions to provide a final food product that complies with the limitations provided in paragraph (b) of this section.

(d) In the standardized foods listed in paragraph (b) of this section, the additives are used only in compliance with the applicable standards of identity for such foods.

§ 172.130 Dehydroacetic acid.

The food additive dehydroacetic acid and/or its sodium salt may be safely used in accordance with the following prescribed conditions:

(a) The food additive meets the following specifications:

Dehydroacetic acid: Melting point, 109° C–111° C; assay, minimum 98 percent (dry basis).

Sodium salt of dehydroacetic acid: Assay, minimum 98 percent (dry basis).

(b) It is used or intended for use as a preservative for cut or peeled squash, and is so used that no more than 65 parts per million expressed as dehydroacetic acid remains in or on the prepared squash.

(c) The label or labeling of any package of the additive intended for use in food shall bear adequate directions for use to insure compliance with this section.

§ 172.135 Disodium EDTA.

The food additive disodium EDTA (disodium ethylenediaminetetraacetate) may be safely used in designated foods for the purposes and in accordance with the following prescribed conditions:

(a) The additive contains a minimum of 99 percent disodium ethylenediaminetetraacetate dihydrate ($C_{10}H_{14}O_8N_2Na_2 \cdot 2H_2O$).

(b) It is used or intended for use as follows:

(1) Alone, in the following foods at not to exceed the levels prescribed, calculated as anhydrous calcium disodium EDTA:

Food	Limitation (parts per million)	Use
Aqueous multivitamin preparations.	130	With iron salts as a stabilizer for vitamin B_{12} in liquid multivitamin preparations.
Canned blackeyed peas.	145	Promote color retention.
Canned cooked chickpeas.	165	Do.
Canned kidney beans.	165	Preservative.
Canned strawberry pie filling.	360	Promote color retention.
Cooked sausage	36	As a cure accelerator with sodium ascorbate or ascorbic acid.
Dressings, nonstandardized.	75	Preservative.
French dressing	75	Do.
Frozen white potatoes including cut potatoes.	100	Promote color retention.
Gefilte fish balls or patties in packing medium.	50	Inhibit discoloration.
Mayonnaise	75	Preservative.
Ready-to-eat cereal	[2] 315	Promote color retention.
Products containing dried bananas.		
Salad dressing	75	Preservative.
Sandwich spread	100	Do.
Sauces	75	Do.

[1] Based on total weight of finished product including packing medium.

[2] In dried banana component of cereal product.

(2) With calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate; calcium disodium (ethylenedinitrilo) tetraacetate), in the following foods at not to exceed, in combination, the levels prescribed, calculated as anhydrous $C_{10}H_{12}O_8N_2CaNa_2$:

Food	Limitation (parts per million)	Use
Dressings, nonstandardized	75	Preservative.
French dressing	75	Do.
Mayonnaise	75	Do.
Salad dressing	75	Do.
Sandwich spread	100	Do.
Sauces	75	Do.

(3) Alone, as a sequestrant in the nonnutritive sweeteners that are listed in § 180.37 of this chapter and that, in addition, are designed for aqueous solution: *Provided*, That the amount of the additive, calculated as anhydrous calcium disodium EDTA, does not exceed 0.1 percent by weight of the dry nonnutritive sweetener.

(c) To assure the safe use of the additive:

(1) The label and labeling of the additive container shall bear, in addition to the other information required by the act, the name of the additive.

(2) The label or labeling of the additive container shall bear adequate use directions to provide a final food product that complies with the limitations provided in paragraph (b) of this section.

(d) In the standardized foods listed in paragraph (b) (1) and (2) of this section the additives are used only in compliance with the applicable standards of identity for such foods.

§ 172.140 Ethoxyquin.

(a) Ethoxyquin (1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline) may be safely used as an antioxidant for preservation of color in the production of chili powder, paprika, and ground chili at levels not in excess of 100 parts per million.

(b) In order to provide for the safe use of the additive in feed prepared in accordance with §§ 573.380 and 573.400 of this chapter, tolerances are established for residues of ethoxyquin in or on edible products of animals as follows:

5 parts per million in or on the uncooked fat of meat from animals except poultry.

3 parts per million in or on the uncooked liver and fat of poultry.

0.5 part per million in or on the uncooked muscle meat of animals.

0.5 part per million in poultry eggs.

Zero in milk.

§ 172.145 Heptylparaben.

(a) The food additive heptylparaben is the chemical *n*-heptyl *p*-hydroxybenzoate.

(b) It may be safely used to inhibit microbiological spoilage in accordance with the following prescribed conditions:

(1) In fermented malt beverages in amounts not to exceed 12 parts per million.

(2) In noncarbonated soft drinks and fruit-based beverages in amounts not to exceed 20 parts per million, when standards of identity established under section 401 of the act (21 U.S.C. 341) do not preclude such use.

§ 172.150 4-Hydroxymethyl-2,6-di-*tert*-butylphenol.

The food additive 4-hydroxymethyl-2,6-di-*tert*-butylphenol may be safely used in food in accordance with the following prescribed conditions:

(a) The additive has a solidification point of 140° C–141° C.

(b) The additive is used as an antioxidant alone or in combination with other permitted antioxidants.

(c) The total amount of all antioxidants added to such food shall not exceed 0.02 percent of the oil or fat content of the food, including the essential (volatile) oil content of the food.

§ 172.160 Potassium nitrate.

The food additive potassium nitrate may be safely used as a curing agent in the processing of cod roe, in an amount not to exceed 200 parts per million of the finished roe.

§ 172.170 Sodium nitrate.

The food additive sodium nitrate may be safely used in or on specified foods in accordance with the following prescribed conditions:

(a) It is used or intended for use as follows:

(1) As a preservative and color fixative, with or without sodium nitrite, in smoked, cured sablefish, smoked, cured salmon, and smoked, cured shad, so that the level of sodium nitrate does not exceed 500 parts per million and the level of sodium nitrite does not exceed 200 parts per million in the finished product.

(2) As a preservative and color fixative, with or without sodium nitrite, in meat-curing preparations for the home curing of meat and meat products (including poultry and wild game), with directions for use which limit the amount of sodium nitrate to not more than 500 parts per million in the finished meat product and the amount of sodium nitrite to not more than 200 parts per million in the finished meat product.

(b) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label of the additive or of a mixture containing the additive shall bear:

(i) The name of the additive.

(ii) A statement of the concentration of the additive in any mixture.

(2) If in a retail package intended for household use, the label and labeling of the additive, or of a mixture containing the additive, shall bear adequate directions for use to provide a final food product that complies with the limitations prescribed in paragraph (a) of this section.

(3) If in a retail package intended for household use, the label of the additive or of a mixture containing the additive, shall bear the statement "Keep out of the reach of children".

§ 172.175 Sodium nitrite.

The food additive sodium nitrite may be safely used in or on specified foods in accordance with the following prescribed conditions:

(a) It is used or intended for use as follows:

(1) As a color fixative in smoked cured tunafish products so that the level of sodium nitrite does not exceed 10 parts per million (0.001 percent) in the finished product.

(2) As a preservative and color fixative, with or without sodium nitrate, in smoked, cured sablefish, smoked, cured salmon, and smoked, cured shad so that the level of sodium nitrite does not exceed 200 parts per million and the level of sodium nitrate does not exceed 500 parts per million in the finished product.

(3) As a preservative and color fixative, with sodium nitrate, in meat-curing preparations for the home curing of meat and meat products (including poultry and wild game), with directions for use which limit the amount of sodium nitrite to not more than 200 parts per million in the finished meat product, and the amount of sodium nitrate to not more than 500 parts per million in the finished meat product.

(b) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label of the additive or of a mixture containing the additive shall bear:

(i) The name of the additive.

(ii) A statement of the concentration of the additive in any mixture.

(2) If in a retail package intended for household use, the label and labeling of the additive, or of a mixture containing the additive, shall bear adequate directions for use to provide a final food product which complies with the limitations prescribed in paragraph (a) of this section.

(3) If in a retail package intended for household use, the label of the additive, or of a mixture containing the additive, shall bear the statement "Keep out of the reach of children".

§ 172.177 Sodium nitrite used in processing smoked chub.

The food additive sodium nitrite may be safely used in combination with salt (NaCl) to aid in inhibiting the outgrowth and toxin formation from *Clostridium botulinum* type E in the commercial processing of smoked chub in accordance with the following prescribed conditions:

(a) All fish in smoking establishments shall be clean and wholesome and shall be expeditiously processed, packed, and stored under adequate sanitary conditions in accordance with good manufacturing practice.

(b) The brining procedure is controlled in such a manner that the water phase portion of the edible portion of the finished smoked product has a salt (NaCl) content of not less than 3.5 percent, as measured in the loin muscle, and the sodium nitrite content of the edible portion of the finished smoked product is not less than 100 parts per million and not greater than 200 parts per million, as measured in the loin muscle.

(c) Smoked chub shall be heated by a controlled heat process which provides a monitoring system positioned in as many strategic locations in the smokehouse as necessary to assure a continuous temperature throughout each fish of at least 160 °F for a minimum of 30 minutes.

(d) The finished product shall be cooled to a temperature of 50 ° F or below within 3 hours after smoking and further cooled to a temperature of 38 ° F or below within 12 hours after smoking. A temperature of 38 ° F or below shall be maintained during all subsequent storage and distribution. All shipping containers, retail packages, and shipping records shall indicate with appropriate notice the perishable nature of the product and specify that the product shall be held under refrigeration (38 ° F or below) until consumed.

(e) To assure safe use of the additive:

(1) The label and labeling of the additive container shall bear, in addition to the other information required by the act, the name of the additive.

(2) The label or labeling of the additive container shall bear adequate directions to assure use in compliance with the provisions of this section.

§ 172.180 Stannous chloride.

The food additive stannous chloride may be safely used for color retention in asparagus packed in glass, with lids lined with an inert material, in an amount not to exceed 20 parts per million calculated as tin (Sn).

§ 172.185 TBHQ.

The food additive TBHQ, which is the chemical 2-(1,1-dimethylethyl)-1,4-benzenediol (Chemical Abstracts Service Registry Number 1948-33-0), also known as tertiary butylhydroquinone, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive has a melting point of 126.5° C–128.5° C.

(b) It is used as an antioxidant alone or in combination with BHA and/or BHT.

(c) The total antioxidant content of a food containing the additive will not exceed 0.02 percent of the oil or fat content of the food, including the essential (volatile) oil content of the food.

§ 172.190 THBP.

The food additive THBP (2,4,5-trihydroxybutyrophenone) may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive has a melting point of 140° C–153° C.

(b) It is used as an antioxidant alone or in combination with other permitted antioxidants.

(c) The total antioxidant content of a food containing the additive will not exceed 0.02 percent of the oil or fat content of the food, including the essential (volatile) oil content of the food.

Subpart C—Coatings, Films and Related Substances

§ 172.210 Coatings on fresh citrus fruit.

Coatings may be applied to fresh citrus fruit for protection of the fruit in accordance with the following conditions:

(a) The coating is applied in the minimum amount required to accomplish the intended effect.

(b) The coating may be formulated from the following components, each used in the minimum quantity required to accomplish the intended effect:

(1) Substances generally recognized as safe for the purpose or previously sanctioned for the purpose.

(2) One or more of the following:

Component	*Limitations*
Fatty acids	Complying with § 172.860.
Oleic acid derived from tall oil fatty acids.	Complying with § 172.862.
Partially hydrogenated rosin	Catalytically hydrogenated to a maximum refractive index of 1.5012 at 100° C. Color of WG or paler.
Pentaerythritol ester of maleic anhydride-modified wood rosin.	Acid number of 134–145; drop-softening point of 127° C–137° C; saponification number of less than 280; and a color of M or paler.
Do	Acid number of 176–186; drop-softening point of 110° C–118° C; saponification number of less than 230; and a color of M or paler.
Polyethylene glycol	Complying with § 172.820. As a defoamer and dispersing adjuvant.
Sodium lauryl sulfate	Complying with § 172.822. As a film former.
Wood rosin	Color of K or paler.

(3) In lieu of the components listed in paragraph (b) (2) and (4) of this section, the following copolymer and one or more of the listed adjuvants.

Component	*Limitations*
Vinyl chloride-vinylidene chloride copolymer.	As an aqueous dispersion containing a minimum of 75 percent water when applied.
Polyethylene glycol	Complying with § 172.820. As a defoamer and dispersing adjuvant.
Polyvinylpyrrolidone	Do.
Potassium persulfate	Do.
Propylene glycol alginate	Do.
Sodium decylbenzenesulfonate	Do.

(4) In lieu of the components listed in paragraph (b) (2) and (3) of this section, the following rosin derivative and either or both of the listed adjuvants:

Component	*Limitations*
Calcium salt or partially dimerized rosin.	Having a maximum drop-softening point of 197°C and a color of H or paler. It is prepared by reaction with not more than 7 parts hydrated lime per 100 parts of partially dimerized rosin. The partially dimerized rosin is rosin that has been dimerized by sulfuric acid catalyst to a drop-softening point of 95° C to 105° C and a color of WG or paler.
Petroleum naphtha	As adjuvant. Complying with § 172.250.
Sperm oil	As adjuvant.

§ 172.215 Coumarone-indene resin.

The food additive coumarone-indene resin may be safely used on grapefruit, lemons, limes, oranges, tangelos, and tangerines in accordance with the following prescribed conditions:

(a) The food additive is manufactured by the polymerization of a crude, heavy coal-tar solvent naphtha meeting the following specifications:

(1) It is a mixture of indene, indan (hydrindene), substituted benzenes, and related compounds.

(2) It contains no more than 0.25 percent tar bases.

(3) 95 percent distills in the range 167° C–184° C.

(b) The food additive meets the following specifications:

(1) Soft point, ring and ball: 126° C minimum as determined by the American Society for Testing Materials Method No. E–28–51T.

(2) Refractive index $\left(\frac{n^{25}}{D}\right)$ 1.63–1.64.

(c) It is used or intended for use as a protective coating for grapefruit, lemons, limes, oranges, tangelos, and tangerines whereby the maximum amount of the resin remaining on the fruit does not exceed 200 parts per million on a fresh-weight basis.

(d) To assure safe use of the additive:

(1) The label of the market package or any intermediate premix of the additive shall bear, in addition to the other information required by the act:

(i) The name of the additive, coumarone-indene resin.

(ii) A statement of the concentration of the additive therein.

(2) The label or accompanying labeling shall bear adequate directions that, if followed, will result in a finished food not in conflict with the requirements of this section.

§ 172.225 Methyl esters of fatty acids produced from edible fats and oils.

Methyl esters of fatty acids produced from edible fats and oils may be safely used in food, subject to the following prescribed conditions:

(a) The additive consists of a mixture of methyl esters of fatty acids produced from edible fats and oils and meets the following specifications:

(1) Not less than 90 percent methyl esters of fatty acids.

(2) Not more than 1.5 percent unsaponifiable matter.

(b) The additive is used or intended for use at a level not to exceed 3 percent by weight in an aqueous emulsion in dehydrating grapes to produce raisins, whereby the residue of the additive on the raisins does not exceed 200 parts per million.

§ 172.230 Microcapsules for flavoring oils.

Microcapsules may be safely used for encapsulating discrete particles of fla-

voring oils that are generally recognized as safe for their intended use or are regulated under this part, in accordance with the following conditions:

(a) The microcapsules may be formulated from the following components, each used in the minimum quantity required to accomplish the intended effect:

(1) Substances generally recognized as safe for the purpose.

(2) One or more of the following:

Component	*Limitations*
Succinylated gelatin.	Not to exceed 15 percent by combined weight of the microcapsule and flavoring oil. Succinic acid content of the gelatin is 4.5 to 5.5 percent.
Arabinogalactan	Complying with § 172.610; as adjuvant.
Silicon dioxide	Complying with § 172.480; as adjuvant.

(3) In lieu of the components listed in paragraph (a)(2) of this section, the following components:

Component	*Limitations*
Glutaraldehyde	As cross-linking agent for insolubilizing a coacervate of gum arabic and gelatin.
n-Octyl alcohol	As a defoamer.

(b) The microcapsules may be used for encapsulating authorized flavoring oils for use, in accordance with good manufacturing practice, in foods for which standards of identity established under section 401 of the act do not preclude such use, except that microcapsules formulated from components listed in paragraph (a)(2) of this section may be used only for encapsulating lemon oil, distilled lime oil, orange oil, peppermint oil, and spearmint oil for use in dry mixes for puddings and gelatin desserts.

§ 172.235 Morpholine.

Morpholine may be safely used as a component of food, subject to the following restrictions.

(a) It is used as the salt(s) of one or more of the fatty acids meeting the requirements of § 172.860, as a component of protective coatings applied to fresh fruits and vegetables.

(b) It is used at a level not in excess of that reasonably required to produce its intended effect.

§ 172.250 Petroleum naphtha.

Petroleum naphtha may be safely used in food in accordance with the following conditions:

(a) The additive is a mixture of liquid hydrocarbons, essentially paraffinic and naphthenic in nature obtained from petroleum,

(b) The additive is refined to meet the following specifications when subjected to the procedures described in this paragraph.

(1) Boiling-point range: 175° F–300° F.

(2) Nonvolatile residue: 0.002 gram per 100 milliliters maximum.

(3) Ultraviolet absorbance limits, as follows:

Wavelength (millimicrons)	*Maximum absorbance per centimeter optical pathlength*
280–289	0.15
290–299	.13
300–359	.08
360–400	.02

ANALYTICAL SPECIFICATION FOR PETROLEUM NAPHTHA

GENERAL INSTRUCTIONS

All glassware should be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure, it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of petroleum naphtha samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

Separatory funnels. 250-milliliter, and 2,000-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Erlenmeyer flask. 125-milliliter with 24/40 standard taper neck.

Evaporation flask. 250-milliliter capacity all-glass flask equipped with 24/40 standard taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of the contained liquid to be evaporated.

Condenser. 24/40 joints, fitted with drying tube, length optional.

Spectrophotometric cells. Fused quartz cells, optical path length in the range of 5.000 centimeters ±0.005 centimeter; also for checking spectrophotometer performance only, optical path length in the range 1.000 centimeter ±0.005 centimeter. With distilled water in the cells, determine any absorbance difference.

Spectrophotometer. Spectral range 250–400 mμ with spectral slit width of 2 mμ or less; under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.
Absorbance accuracy,[1] ±0.05 at 0.4 absorbance.
Wavelength repeatability, ±0.2 millimicron.
Wavelength accuracy, ±1.0 millimicron.

Ultraviolet lamp. Long wavelength (3400–3800A°).

REAGENTS

Isooctane (2,2,4-trimethylpentane). Use 180 milliliters in a 250-milliliter Erlenmeyer flask, add 1 milliliter of purified *n*-hexadecane, insert the head assembly, allow nitrogen gas to flow into the inlet tube and connect the outlet tube to a solvent trap and vacuum line in such a way as to prevent any back flow of condensate into the flask. The contents of the flask are evaporated on a steam bath until 1 milliliter of residue remains. Dissolve the 1 milliliter of hexadecane residue in isooctane and make up to 25 milliliters. Determine the absorbance in a 5-centimeter path length cell compared to isooctane as reference. The absorbance should not exceed 0.01 per centimeter path length between 280–400 mμ. If necessary, isooctane may be purified by passage through a column of activated silica gel (Grade 12, Davidson Chemical Co., Baltimore, Md., or equivalent) or by distillation.

Methyl alcohol, A.C.S. reagent grade. Use 10 milliliters and proceed as with isooctane. The absorbance per centimeter of path length should be 0.00 between 280–400 mμ. Methyl alcohol may be purified by simple distillation or by refluxing in the presence of potassium hydroxide (10 grams/2 liters) and zinc dust (25 grams/2 liters) for 3 hours followed by distillation.

n-Hexadecane, 99 percent olefin-free. Dilute 1.0 milliliter of *n*-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 5-centimeter cell compared to isooctane as reference between 280–400 mμ. The absorbance per centimeter path length shall not exceed 0.00 in this range. Purify, if necessary, by percolation through activated silica gel or by distillation.

Sodium borohydride. 98 percent.

Water. All distilled water must be extracted with isooctane before use. A series of three successive extracts of 1.5 liters of distilled water with 100-milliliter portions of isooctane is satisfactory.

PROCEDURE

Determination of ultraviolet absorbance. Add a 25-milliliter aliquot of the hydrocarbon solvent together with 1 milliliter of hexadecane to the 125-milliliter Erlenmeyer flask. While flushing with nitrogen, evaporate to 1 milliliter on a steam bath. Nitrogen is admitted through a 8±1-milliliter outer-diameter tube, drawn out into a 2±1-centimeter long and 1±0.5-millimeter inner-diameter capillary tip. This is positioned so that the capillary tip extends 4 centimeters into the flask. The nitrogen flow rate is such that the surface of the liquid is barely disturbed. After the volume is reduced to that of the 1 milliliter of hexadecane, the flask is left on the steam bath for 10 more minutes before removing. Add 10 milliliters of purified isooctane to the flask and reevaporate the solution to a 1-milliliter volume in the same manner as described above, except do not heat for an added 10 minutes. Repeat this operation twice more. Let the flask cool.

Add 10 milliliters of methyl alcohol and about 0.3 gram of sodium borohydride. (Minimize exposure of the borohydride to the atmosphere; a measuring dipper may be used.) Immediately fit a water-cooled condenser equipped with a 24/40 joint and with a drying tube into the flask, mix until the sodium borohydride is dissolved, and allow to stand for 30 minutes at room temprature, with intermittent swirling. At the end of this time, disconnect the flask and evaporate the methyl alcohol on the steam bath under nitrogen until sodium borohydride begins to drop out of solution. Remove the flask and let it cool.

Add 6 milliliters of isooctane to the flask and swirl to wash the crystalline slurry. Carefully transfer the isooctane extract to a 250-milliliter separatory funnel. Dissolve

[1] As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, 1949. The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons.

the crystals in the flask with about 25 milliliters of distilled water and pour this also into the separatory funnel. Adjust the water volume in the separatory funnel to about 100 milliliters and shake for 1 minute. After separation of the layers, draw off the aqueous layer into a second 250-milliliter separatory funnel. Transfer the hydrocarbon layer in the first funnel to a 25-milliliter volumetric flask.

Carefully wash the Erlenmeyer flask with an additional 6 milliliters of isooctane, swirl, and transfer to the second separatory funnel. Shake the funnel for 1 minute. After separation of the layers, draw off the aqueous layer into the first separatory funnel. Transfer the isooctane in the second funnel to the volumetric flask. Again wash the Erlenmeyer flask with an additional 6 milliliters of isooctane, swirl, and transfer to the first separatory funnel. Shake the funnel for 1 minute. After separation of the layers, draw off the aqueous layer and discard. Transfer the isooctane layer to the volumetric flask and adjust the volume to 25 milliliters of isooctane. Mix the contents well, then transfer to the first separatory funnel and wash twice with 50-milliliter portions of distilled water. Discard the aqueous layers after each wash.

Determine the ultraviolet absorbance of the isooctane extract in 5-centimeter path length cells compared to isooctane as reference between 280–400 mμ. Determine a reagent blank concurrently with the sample, using 25 milliliters of purified isooctane instead of a solvent sample and measuring the ultraviolet absorbance of the blank between 280–400mμ.

The reagent blank absorbance should not exceed 0.04 per centimeter path length between 280–289 mμ; 0.020 between 290–359 mμ; and 0.010 between 360–400 mμ.

Determination of boiling-point range. Use ASTM Method D–86.

Determination of nonvolatile residue. For hydrocarbons boiling below 250° F determine the nonvolatile residue by ASTM Method D–1353; for those boiling above 250° F, use ASTM Method D–381.

(c) Petroleum naphtha containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. Petroleum naphtha may contain antioxidants authorized for use in food in an amount not to exceed that reasonably required to accomplish the intended effect or to exceed any prescribed limitations.

(d) Petroleum naphtha is used or intended for use as a solvent in protective coatings on fresh citrus fruit in compliance with § 172.210.

§ 172.255 Polyacrylamide.

Polyacrylamide containing not more than 0.2 percent of acrylamide monomer may be safely used as a film former in the imprinting of soft-shell gelatin capsules when the amount used is not in excess of the minimum required to produce the intended effect.

§ 172.260 Oxidized polyethylene.

Oxidized polyethylene may be safely used as a component of food, subject to the following restrictions:

(a) Oxidized polyethylene is the basic resin produced by the mild air oxidation of polyethylene. The polyethylene used in the oxidation process conforms to the density, maximum *n*-hexane extractable fraction, and maximum xylene soluble fraction specifications prescribed in item 2.3 of the table in § 177.1520(c) of this chapter. The oxidized polyethylene has a minimum number average molecular weight of 1,200, as determined by high temperature vapor pressure osmometry; contains a maximum of 5 percent by weight of total oxygen; and has an acid value of 9 to 19.

(b) The additive is used or intended for use as a protective coating or component of protective coatings for fresh avocados, bananas, beets, coconuts, eggplant, garlic, grapefruit, lemons, limes, mango, muskmelons, onions, oranges, papaya, peas (in pods), pineapple, plantain, pumpkin, rutabaga, squash (acorn), sweetpotatoes, tangerines, turnips, watermelon, Brazil nuts, chestnuts, filberts, hazelnuts, pecans, and walnuts (all nuts in shells).

(c) The additive is used in accordance with good manufacturing practice and in an amount not to exceed that required to produce the intended effect.

§ 172.275 Synthetic paraffin and succinic derivatives.

Synthetic paraffin and succinic derivatives identified in this section may be safely used as a component of food, subject to the following restrictions:

(a) The additive is prepared with 50 percent Fischer-Tropsch process synthetic paraffin, meeting the definition and specifications of § 172.615, and 50 percent of such synthetic paraffin to which is bonded succinic anhydride and succinic acid derivatives of isopropyl alcohol, polyethylene glycol, and polypropylene glycol. It consists of a mixture of the Fischer-Tropsch process paraffin (alkane), alkyl succinic anhydride, alkyl succinic anhydride isopropyl half ester, dialkyl succinic anhydride polyethylene glycol half ester, and dialkyl succinic anhydride polypropylene glycol half ester, where the alkane (alkyl) has a chain length of 30–70 carbon atoms and the polyethylene and polypropylene glycols have molecular weights of 600 and 260, respectively.

(b) The additive meets the following specifications: Molecular weight, 880–930; melting point, 215°–217° F; acid number, 43–47; and saponification number, 75–78.

(c) It is used or intended for use as a protective coating or component of protective coatings for fresh grapefruit, lemons, limes, muskmelons, oranges, sweetpotatoes, and tangerines.

(d) It is used in an amount not to exceed that required to produce the intended effect.

§ 172.280 Terpene resin.

The food additive terpene resin may be safely used in accordance with the following prescribed conditions:

(a) The food additive is the beta-pinene polymer obtained by polymerizing terpene hydrocarbons derived from wood. It has a softening point of 112° C —118° C, as determined by ASTM method E–28–51T.

(b) It is used or intended for use as follows:

(1) As a moisture barrier on soft gelatin capsules in an amount not to exceed 0.07 percent of the weight of the capsule.

(2) As a moisture barrier on powders of ascorbic acid or its salts in an amount not to exceed 7 percent of the weight of the powder.

Subpart D—Special Dietary and Nutritional Additives

§ 172.310 Aluminum nicotinate.

Aluminum nicotinate may be safely used as a source of niacin in foods for special dietary use. A statement of the concentration of the additive, expressed as niacin, shall appear on the label of the food additive container or on that of any intermediate premix prepared therefrom.

§ 172.315 Nicotinamide-ascorbic acid complex.

Nicotinamide-ascorbic acid complex may be safely used in accordance with the following prescribed conditions:

(a) The additive is the product of the controlled reaction between ascorbic acid and nicotinamide, melting in the range 141°C to 145°C.

(b) It is used as a source of ascorbic acid and nicotinamide in multivitamin preparations.

§ 172.320 Amino acids.

The food additive amino acids may be safely used as nutrients added to foods in accordance with the following conditions:

(a) The food additive consists of one or more of the following individual amino acids in the free, hydrated or anhydrous form or as the hydrochloride, sodium or potassium salts:

L-Alanine
L-Arginine
L-Asparagine
L-Aspartic acid
L-Cysteine
L-Cystine
L-Glutamic acid
L-Glutamine
Glycine
L-Histidine
L-Isoleucine
L-Leucine
L-Lysine
DL-Methionine (not for infant foods)
L-Methionine
L-Phenylalanine
L-Proline
L-Serine
L-Threonine
L-Tryptophan
L-Tyrosine
L-Valine

(b) The food additive meets the following specifications:

(1) As found in "Food Chemicals Codex," National Academy of Sciences-National Research Council (NAS–NRC), 2nd Edition (1972)[1] for the following:

L-Alanine
L-Arginine
L-Arginine Monohydrochloride
L-Cysteine Monohydrochloride
L-Cystine
Glycine
L-Leucine
DL-Methionine
L-Methionine
L-Tryptophan

[1] Copies may be obtained from: The National Academy of Sciences, 2101 Constitution Ave. NW., Washington, D.C. 20037.

L-Phenylalanine
L-Proline
L-Serine
L-Threonine
Glutamic Acid Hydrochloride
L-Isoleucine
L-Lysine Monohydrochloride
Monopotassium L-glutamate
L-Tyrosine
L-Valine

(2) As found in "Specifications and Criteria for Biochemical Compounds," NAS–NRC Publication, 3rd Edition (1972)[1] for the following:

L-Asparagine
L-Aspartic acid
L-Glutamine
L-Histidine

(c) The additive(s) is used or intended for use to significantly improve the biological quality of the total protein in a food containing naturally occurring primarily-intact protein that is considered a significant dietary protein source, provided that:

(1) A reasonable daily adult intake of the finished food furnishes at least 6.5 grams of naturally occurring primarily intact protein (based upon 10 percent of the daily allowance for the "reference" adult male recommended by the National Academy of Sciences in "Recommended Dietary Allowances," NAS Publication No. 1694, 7th Edition (1968)).[1]

(2) The additive(s) results in a protein efficiency ratio (PER) of protein in the finished ready-to-eat food equivalent to casein as determined by the method specified in paragraph (d) of this section.

(3) Each amino acid (or combination of the minimum number necessary to achieve a statistically significant increase) added results in a statistically significant increase in the PER as determined by the method described in paragraph (d) of this section. The minimum amount of the amino acid(s) to achieve the desired effect must be used and the increase in PER over the primarily-intact naturally occurring protein in the food must be substantiated as a statistically significant difference with at least a probability (P) value of less than 0.05.

(4) The amount of the additive added for nutritive purposes plus the amount naturally present in free and combined (as protein) form does not exceed the following levels of amino acids expressed as percent by weight of the total protein of the finished food:

	Percent by weight of total protein (expressed as free amino acid)
L-Alanine	6.1
L-Arginine	6.6
L-Aspartic acid (including L-asparagine)	7.0
L-Cystine (including L-cysteine)	2.3
L-Glutamic acid (including L-glutamine)	12.4
Glycine	3.5
L-Histidine	2.4
L-Isoleucine	6.6
L-Leucine	8.8
L-Lysine	6.4
L- and DL-Methionine	3.1
L-Phenylalanine	5.8
L-Proline	4.2
L-Serine	8.4
L-Threonine	5.0
L-Tryptophan	1.6
L-Tyrosine	4.3
L-Valine	7.4

[1] Copies may be obtained from: The National Academy of Sciences, 2101 Constitution Ave. NW., Washington, D.C. 20037.

(d) Compliance with the limitations concerning PER under paragraph (c) of this section shall be determined by the method described in sections 39.166–39.170, "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Edition (1970).[2] Each manufacturer or person employing the additive(s) under the provisions of this section shall keep and maintain throughout the period of his use of the additive(s) and for a minimum of 3 years thereafter, records of the tests required by this paragraph and other records required to assure effectiveness and compliance with this regulation and shall make such records available upon request at all reasonable hours by any officer or employee of the Food and Drug Administration, or any other officer or employee acting on behalf of the Secretary of Health, Education, and Welfare and shall permit such officer or employee to conduct such inventories of raw and finished materials on hand as he deems necessary and otherwise to check the correctness of such records.

(e) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the act, the following:

(1) The name of the amino acid(s) contained therein including the specific optical and chemical form.

(2) The amounts of each amino acid contained in any mixture.

(3) Adequate directions for use to provide a finished food meeting the limitations prescribed by paragraph (c) of this section.

(f) The food additive amino acids added as nutrients to special dietary foods that are intended for use solely under medical supervision to meet nutritional requirements in specific medical conditions and comply with the requirements of Part 105 of this chapter are exempt from the limitations in paragraphs (c) and (d) of this section and may be used in such foods at levels not to exceed good manufacturing practices.

§ 172.325 Bakers yeast protein.

Bakers yeast protein may be safely used in food in accordance with the following conditions:

(a) Bakers yeast protein is the insoluble proteinaceous material remaining after the mechanical rupture of yeast cells of *Saccharomyces cerevisiae* and removal of whole cell walls by centrifugation and separation of soluble cellular materials.

[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

(b) The additive meets the following specifications on a dry weight basis:

(1) Zinc salts less than 500 parts per million (ppm) as zinc.

(2) Nucleic acid less than 2 percent.

(3) Less than 0.3 ppm arsenic, 0.1 ppm cadmium, 0.4 ppm lead, 0.05 ppm mercury, and 0.3 ppm selenium.

(c) The viable microbial content of the finished ingredient is:

(1) Less than 10,000 organisms/gram by aerobic plate count.

(2) Less than 10 yeasts and molds/gram.

(3) Negative for *Salmonella, E. coli*, coagulase positive *Staphylococci, Clostridium perfringens, Clostridium botulinum*, or any other recognized microbial pathogen or any harmful microbial toxin.

(d) The ingredient is used in food as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

§ 172.330 Calcium pantothenate, calcium chloride double salt.

The food additive calcium chloride double salt of calcium pantothenate may be safely used in foods for special dietary uses in accordance with good manufacturing practice and under the following prescribed conditions:

(a) The food additive is of the *d* (dextrorotatory) or the *dl* (racemic) form.

(b) To assure safe use of the additive, the label and labeling of the food additive container, or that of any intermediate premixes prepared therefrom, shall bear, in addition to the other information required by the act, the following:

(1) The name of the additive "calcium chloride double salt of *d*-calcium pantothenate" or "calcium chloride double salt of *dl*-calcium pantothenate", whichever is appropriate.

(2) A statement of the appropriate concentration of the additive, expressed as pantothenic acid.

§ 172.335 D-Pantothenamide.

The food additive D-pantothenamide as a source of pantothenic acid activity, may be safely used in foods for special dietary use in an amount not in excess of that reasonably required to produce its intended effect.

§ 172.345 Folic acid (folacin).

Folic acid (folacin) may be safely added to a food for its vitamin property, provided the maximum intake of the food as may be consumed during a period of 1 day, or as directed for use in the case of a dietary supplement, will not result in daily ingestion of the additive in excess of 0.4 milligram for foods labeled without reference to age or physiological state; and when age or the conditions of pregnancy or lactation are specified, in excess of 0.1 milligram for infants, 0.3 milligram for children under 4 years of age, 0.4 milligram for adults and children 4 or more years of age, and 0.8 milligram for pregnant or lactating women.

§ 172.350 Fumaric acid and salts or fumaric acid.

Fumaric acid and its calcium, ferrous, magnesium, potassium, and sodium salts may be safely used in food in accordance

with the following prescribed conditions:

(a) The additives meet the following specifications:

(1) Fumaric acid contains a minimum of 99.5 percent by weight of fumaric acid, calculated on the anhydrous basis.

(2) The calcium, magnesium, potassium, and sodium salts contain a minimum of 99 percent by weight of the respective salt, calculated on the anhydrous basis. Ferrous fumarate contains a minimum of 31.3 percent total iron and not more than 2 percent ferric iron.

(b) With the exception of ferrous fumarate, fumaric acid and the named salts are used singly or in combination in food at a level not in excess of the amount reasonably required to accomplish the intended effect.

(c) Ferrous fumarate is used as a source of iron in foods for special dietary use, when the use is consistent with good nutrition practice.

§ 172.365 Kelp.

Kelp may be safely added to a food as a source of the essential mineral iodine, provided the maximum intake of the food as may be consumed during a period of one day, or as directed for use in the case of a dietary supplement, will not result in daily ingestion of the additive so as to provide a total amount of iodine in excess of 225 micrograms for foods labeled without reference to age or physiological state; and when age or the conditions of pregnancy or lactation are specified, in excess of 45 micrograms for infants, 105 micrograms for children under 4 years of age, 225 micrograms for adults and children 4 or more years of age, and 300 micrograms for pregnant or lactating women. The food additive kelp is the dehydrated, ground product prepared from *Macrocystis pyrifera*, *Laminaria digitata*, *Laminaria saccharina*, and *Laminaria cloustoni*.

§ 172.370 Iron-choline citrate complex.

Iron-choline citrate complex made by reacting approximately equimolecular quantities of ferric hydroxide, choline, and citric acid may be safely used as a source of iron in foods for special dietary use.

§ 172.375 Potassium iodide.

The food additive potassium iodide may be safely used in accordance with the following prescribed conditions:

(a) Potassium iodide may be safely added to a food as a source of the essential mineral iodine, provided the maximum intake of the food as may be consumed during a period of one day, or as directed for use in the case of a dietary supplement, will not result in daily ingestion of the additive so as to provide a total amount of iodine in excess of 225 micrograms for foods labeled without reference to age or physiological state; and when age or the conditions of pregnancy or lactation are specified, in excess of 45 micrograms for infants, 105 micrograms for children under 4 years of age, 225 micrograms for adults and children 4 or more years of age, and 300 micrograms for pregnant or lactating women.

(b) To assure safe use of the additive, in addition to the other information required by the act, the label of the additive shall bear:

(1) The name of the additive.

(2) A statement of the concentration of the additive in any mixture.

§ 172.385 Whole fish protein concentrate.

The food additive whole fish protein concentrate may be safely used as a food supplement in accordance with the following prescribed conditions:

(a) The additive is derived from whole, wholesome hake and hakelike fish, herring of the genera *Clupea*, menhaden, and anchovy of the species *Engraulis mordax*, handled expeditiously and under sanitary conditions in accordance with good manufacturing practices recognized as proper for fish that are used in other forms for human food.

(b) The additive consists essentially of a dried fish protein processed from the whole fish without removal of heads, fins, tails, viscera, or intestinal contents. It is prepared by solvent extraction of fat and moisture with isopropyl alcohol or with ethylene dichloride followed by isopropyl alcohol, except that the additive derived from herring, menhaden and anchovy is prepared by solvent extraction with isopropyl alcohol alone. Solvent residues are reduced by conventional heat drying and/or microwave radiation and there is a partial removal of bone.

(c) The food additive meets the following specifications:

(1) Protein content (N x 6.25) shall not be less than 75 percent by weight of the final product, as determined by the method described in Official Methods of Analysis of the Association of Official Agricultural Chemists, section 2.044, 10th Edition (1965). Protein quality shall not be less than 100, as determined by the method described in sections 39.133–39.137 of such 10th Edition.

(2) Moisture content shall not exceed 10 percent by weight of the final product, as determined by the method described in section 23.003 of said 10th Edition.

(3) Fat content shall not exceed 0.5 percent by weight of the final product, as determined by the method described in section 23.005 of said 10th Edition.

(4) The additive may contain residues of isopropyl alcohol and ethylene dichloride not in excess of 250 parts per million and 5 parts per million, respectively, when used as solvents in the extraction process.

(5) Microwave radiation meeting the requirements of § 179.30 of this chapter may be used to reduce residues of the solvents used in the extraction process.

(6) The additive shall contain not in excess of 100 parts per million fluorides (expressed as F).

(7) The additive shall be free of *Escherichia coli* and pathogenic organisms, including *Salmonella*, and shall have a total bacterial plate count of not more than 10,000 per gram.

(8) The additive shall have no more than a faint characteristic fish odor and taste.

(d) When the additive is used or intended for use in the household as a protein supplement in food for regular consumption by children up to 8 years of age, the amount of the additive from this source shall not exceed 20 grams per day (about one heaping tablespoon).

(e) When the additive is used as a protein supplement in manufactured food, the total fluoride content (expressed as F) of the finished food shall not exceed 8 ppm based on the dry weight of the food product.

(f) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label of consumer-sized or bulk containers of the additive shall bear the name "whole fish protein concentrate".

(2) The label or labeling of containers of the additive shall bear adequate directions for use to comply with the limitations prescribed by paragraphs (d) and (e) of this section.

(3) Labels of manufactured foods containing the additive shall bear, in the ingredient statement, the name of the additive, "whole fish protein concentrate" in the proper order of decreasing predominance in the finished food.

§ 172.395 Xylitol.

Xylitol may be safely used in foods for special dietary uses, provided the amount used is not greater than that required to produce its intended effect.

Subpart E—Anticaking Agents

§ 172.410 Calcium silicate.

Calcium silicate, including synthetic calcium silicate, may be safely used in food in accordance with the following prescribed conditions:

(a) It is used as an anticaking agent in food in an amount not in excess of that reasonably required to produce its intended effect.

(b) It will not exceed 2 percent by weight of the food, except that it may be present up to 5 percent by weight of baking power.

§ 172.430 Iron ammonium citrate.

Iron ammonium citrate may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is the chemical green ferric ammonium citrate.

(b) The additive is used, or intended for use as an anticaking agent in salt for human consumption so that the level of iron ammonium citrate does not exceed 25 parts per million (0.0025 percent) in the finished salt.

(c) To assure safe use of the additive the label or labeling of the additive shall bear, in addition to the other information required by the act:

(1) The name of the additive.

(2) Adequate directions to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

§ 172.480 Silicon dioxide.

The food additive silicon dioxide may be safely used in food in accordance with the following conditions:

(a) The food additive is manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect.

(b) It is used as an anticaking agent, subject to the following conditions:

(1) It is used in only those foods in which the additive has been demonstrated to have an anticaking effect.

(2) It is used in an amount not in excess of that reasonably required to produce its intended effect.

(3) [Reserved]

(4) It is used in an amount not to exceed 2 percent by weight of the food.

(c) It is used or intended for use as a stabilizer in the production of beer, and is removed from the beer by filtration prior to final processing.

(d) It is used or intended for use as an adsorbent for *dl*-*α*-tocopheryl acetate and pantothenyl alcohol in tableted foods for special dietary use, in an amount not greater than that required to accomplish the intended physical or technical effect.

§ 172.490 Yellow prussiate of soda.

(a) The food additive yellow prussiate of soda (sodium ferrocyanide decahydrate; $Na_4FE(CN_6.10H_2O$) contains a minimum of 99 percent by weight of sodium ferrocyanide decahydrate.

(b) The additive is used or intended for use as an anticaking agent in salt and as an adjuvant in the production of dendritic crystals of salt in an amount needed to produce its intended effect but not in excess of 13 parts per million calculated as anhydrous sodium ferrocyanide.

Subpart F—Flavoring Agents and Related Substances

§ 172.510 Natural flavoring substances and natural substances used in conjunction with flavors.

Natural flavoring substances and natural adjuvants may be safely used in food in accordance with the following conditions.

(a) They are used in the minimum quantity required to produce their intended physical or technical effect, and in accordance with all the principles of good manufacturing practice.

(b) In the appropriate forms (plant parts, fluid and solid extracts, concretes, absolutes, oils, gums, balsams, resins, oleoresins, waxes, and distillates) they consist of one or more of the following, used alone or in combination with flavoring substances and adjuvants generally recognized as safe in food, previously sanctioned for such use, or regulated in any section of this part.

Common name	Scientific name	Limitations
Aloe	*Aloe perryi* Baker, *A. barbadensis* Mill., *A. ferax* Mill., and hybrids of this sp. with *A. africana* Mill. and *A. spicata* Baker.	
Althea root and flowers	*Althea officinalis* L.	
Amyris (West Indian sandalwood).	*Amyris balsamifera* L.	
Angola weed	*Roccella fuciformis* Ach	In alcoholic beverages only.
Arnica flowers	*Arnica montana* L., *A. fulgens* Pursh, *A. sororia* Greene, or *A. cordifolia* Hooker.	Do.
Artemisia (wormwood)	*Artemisia* spp.	Finished food thujone free.[1]
Artichoke leaves	*Cynara scolymus* L.	In alcoholic beverages only.
Beeswax, white (Cire d'abeille).	*Apis mellifera* L.	
Benzoin resin	*Styrax benzoin* Dryander, *S. paralleloneurus* Perkins, *S. tonkinensis* (Pierre) Craib ex Hartwich, or other spp. of the Section *Anthostyrax* of the genus *Styrax*.	
Blackberry bark	*Rubus*, Section *Eubatus*.	
Boldus (boldo) leaves	*Peumus boldus* Mol.	Do.
Boronia flowers	*Boronia megastigma* Nees.	
Bryonia root	*Bryonia alba* L., or *B. dioica* Jacq.	Do.
Buchu leaves	*Barosma betulina* Bartl. et Wendl., *B. crenulata* (L.) Hook. or *B. serratifolia* Willd.	
Buckbean leaves	*Menyanthes trifoliata* L.	Do.
Cajeput	*Melaleuca leucadendron* L. and other *Melaleuca* spp.	
Calumba root	*Jateorhiza palmata* (Lam.) Miers	Do.
Camphor tree	*Cinnamomum camphora* (L.) Nees et Eberm.	Safrole free.
Cascara sagrada	*Rhamnus purshiana* DC.	
Cassie flowers	*Acacia farnesiana* (L.) Willd.	
Castor oil	*Ricinus communis* L.	
Catechu, black	*Acacia catechu* Willd.	
Cedar, white (aborvitae), leaves and twigs.	*Thuja occidentalis* L.	Finished food thujone free.[1]
Centuary	*Centaurium umbellatum* Gilib.	In alcoholic beverages only.
Cherry pits	*Prunus avium* L. or *P. cerasus* L.	Not to exceed 25 p.p.m. prussic acid.
Cherry-laurel leaves	*Prunus laurocerasus* L.	Do.
Chestnut leaves	*Castanea dentata* (Marsh.) Borkh.	
Chirata	*Swertia chirata* Buch.-Ham.	In alcoholic beverages only.
Cinchona, red, bark	*Cinchona succirubra* Pav. or its hybrids.	In beverages only; not more than 83 p.p.m. total cinchona alkaloids in finished beverage.
Cinchona, yellow, bark	*Cinchona ledgeriana* Moens, *C. calisaya* Wedd., or hybrids of these with other spp. of *Cinchona*.	Do.
Copaiba	South American spp. of *Copaifera* L.	
Cork, oak	*Quercus suber* L., or *Q. occidentalis* F. Gay.	In alcoholic beverages only.
Costmary	*Chrysanthemum balsamita* L.	Do.
Costus root	*Saussurea lappa* Clarke.	
Cubeb	*Piper cubeba* L. f.	
Currant, black, buds and leaves.	*Ribes nigrum* L.	
Damiana leaves	*Turnera diffusa* Willd.	
Davana	*Artemisia pallens* Wall.	
Dill, Indian	*Anethum sowa* Roxb. (*Peucedanum graveolens* Benth et Hook., *Anethum graveolens* L.).	
Dittany (fraxinella) roots	*Dictamnus albus* L.	In alcoholic beverages only.
Dittany of Crete	*Origanum dictamnus* L.	
Dragon's blood (draconubin)	*Daemonorops* spp.	
Elder tree leaves	*Sambucus nigra* L.	In alcoholic beverages only; not to exceed 35 p.p.m. prussic acid in the flavor.
Elecampane rhizome and roots	*Inula helenium* L.	In alcoholic beverages only.
Elemi	*Canarium commune* L. or *C. luzonicum* Miq.	
Erigeron	*Erigeron canadense* L.	
Eucalyptus globulus leaves	*Eucalyptus globulus* Labill.	
Fir ("pine") needles and twigs	*Abies sibirica* Ledeb., *A. alba* Mill., *A. sachalinensis* Masters or *A. mayriana* Miyabe et Kudo.	
Fir, balsam, needles and twigs	*Abies balsamea* (L.) Mill.	
Galanga, greater	*Alpinia galanga* Willd.	Do.
Galbanum	*Ferula galbaniflua* Boiss. et Buhse and other *Ferula* spp.	
Gambir (catechu, pale)	*Uncaria gambir* Roxb.	
Genet flowers	*Spartium junceum* L.	
Gentian rhizome and roots	*Gentiana lutea* L.	
Gentian, stemless	*Gentiana acaulis* L.	Do.
Germander, chamaedrys	*Teucrium chamaedrys* L.	Do.
Germander, golden	*Teucrium polium* L.	In alcoholic beverages only.
Guaiac	*Guaiacum officinale* L., *G. santum* L., *Bulnesia sarmienti* Lor.	
Guarana	*Paullinia cupana* HBK.	
Haw, black, bark	*Viburnum prunifolium* L.	
Hemlock needles and twigs	*Tsuga canadensis* (L.) Carr. or *T. heterophylla* (Raf.) Sarg.	
Hyacinth flowers	*Hyacinthus orientalis* L.	
Iceland moss	*Cetraria islandica* Ach.	Do.
Imperatoria	*Peucedanum ostruthium* (L.) Koch (*Imperatoria ostruthium* L.).	
Iva	*Achillea moschata* Jacq.	Do.
Labdanum	*Cistus* spp.	
Lemon-verbena	*Lippia citriodora* HBK.	Do.
Linaloe wood	*Bursera delpechiana* Poiss. and other *Bursera* spp.	
Linden leaves	*Tilia* spp.	Do.
Lovage	*Levisticum officinale* Koch.	
Lungmoss (lungwort)	*Sticta pulmonacea* Ach.	
Maidenhair fern	*Adiantum capillus-veneris* L.	Do.
Maple, mountain	*Acer spicatum* Lam.	
Mimosa (black wattle) flowers	*Acacia decurrens* Willd. var. *dealbata*.	
Mullein flowers	*Verbascum phlomoides* L. or *V. thapsiforme* Schrad.	Do.
Myrrh	*Commiphora molmol* Engl., *C. abyssinica* (Berg) Engl., or other *Commiphora* spp.	

Common name	Scientific name	Limitations
Myrtle leaves	*Myrtus communis* L.	In alcoholic beverages only.
Oak, English, wood	*Quercus robur* L.	Do.
Oak, white, chips	*Quercus alba* L.	
Oak moss	*Evernia prunastri* (L.) Ach., *E. furfuracea* (L.) Mann, and other lichens.	Finished food thujone.
Olibanum	*Boswellia carteri* Birdw. and other *Boswellia* spp.	
Opopanax (bisabolmyrrh)	*Opopanax chironium* Koch (true opopanax) of *Commiphora erythraea* Engl. var. *Llabrecensis*	
Orris root	*Iris germanica* L. (including its variety *florentina* Dykes) and *I. pallida* Lam.	
Pansy	*Viola tricolor* L.	In alcoholic beverages only.
Passion flower	*Passiflora incarnata* L.	
Patchouly	*Pogostemon cablin* Benth. and *P. heyneanus* Benth.	
Peach leaves	*Prunus persica* (L.) Batsch	In alcoholic beverages only; not to exceed 25 p.p.m. prussic acid in the flavor.
Pennyroyal, American	*Hedeoma pulegioides* (L.) Pers.	
Pennyroyal, European	*Mentha pulegium* L.	
Pine, dwarf, needles and twigs	*Pinus mugo* Turra var. *pumilio* (Haenke) Zenari.	
Pine, Scotch, needles and twigs	*Pinus sylvestris* L.	
Pine, white, bark	*Pinus strobus* L.	In alcoholic beverages only.
Pine, white oil	*Pinus palustris* Mill., and other *Pinus* spp.	
Poplar buds	*Populus balsamifera* L. (*P. tacamahacca* Mill.), *P. candicans* Ait., or *P. nigra* L.	Do.
Quassia	*Picrasma excelsa* (Sw.) Planch, or *Quassia amara* L.	
Quebracho bark	*Aspidosperma quebracho-blanco* Schlecht, or (*Quebrachia lorentzii* (Griseb).	*Schinopsis lorentzii* (Griseb.) Engl.
Quillaia (soapbark)	*Quillaja saponaria* Mol.	
Red saunders (red sandal wood).	*Pterocarpus sanalinus* L.	In alcoholic beverages only.
Rhatany root	*Krameria triandra* Ruiz et Pav. or *K. argentea* Mart.	
Rhubarb, garden root	*Rheum rhaponticum* L.	Do.
Rhubarb root	*Rheum officinale* Baill., *R. palmatum* L., or other spp. (excepting *R. rhaponticum* L.) or hybrids of *Rheum* grown in China.	
Roselle	*Hibiscus sabdariffa* L.	Do.
Rosin (colophony)	*Pinus palustris* Mill., and other *Pinus* spp.	Do.
St. Johnswort leaves, flowers, and canlis.	*Hypericum perforatum* L.	Hypericin-free alcohol distillate form only; in alcoholic beverages only.
Sandalwood, white (yellow, or East Indian).	*Santalum album* L.	
Sandarac	*Tetraclinis articulata* (Vahl.), Mast.	In alcoholic beverages only.
Sarsaparilla	*Smilax aristolochiaefolia* Mill., (Mexican sarsaparilla), *S. regelii* Killip et Morton (Honduras sarsaparilla), *S. febrifuga* Kunth (Ecuadorean sarsaparilla), or undetermined *Smilax* spp. (Ecuadorean or Central American sarsaparilla).	
Sassafras leaves	*Sassafras albidum* (Nutt.) Nees.	Safrole free.
Senna, Alexandria	*Cassia acutifolia* Delile.	
Serpentaria (Virginia snakeroot).	*Aristolochia serpentaria* L.	In alcoholic beverages only.
Simaruba bark	*Simaruba amara* Aubl.	Do.
Snakeroot, Canadian (wild ginger).	*Asarum canadense* L.	
Spruce needles and twigs	*Picea glauca* (Moench) Voss or *P. mariana* (Mill.) BSP.	
Storax (styrax)	*Liquidambar orientalis* Mill. or *L. styraciflua* L.	
Tagetes (marigold)	*Tagetes patula* L., *T. erecta* L., or *T. minuta* L. (*T. glandulifera* Schrank).	As oil only.
Tansy	*Tanacetum vulgare* L.	In alcoholic beverages only; finished alcoholic beverage thujone free.[1]
Thistle, blessed (holy thistle)	*Onicus benedictus* L.	In alcoholic beverges only.
Thymus capitatus (Spanish "origanum").	*Thymus capitatus* Hoffmg. et Link.	
Tolu	*Myroxylon balsamum* (L.) Harms.	
Turpentine	*Pinus palustris* Mill. and other *Pinus* spp. which yield terpene oils exclusively.	
Valerian rhizome and roots	*Valeriana officinalis* L.	
Veronica	*Veronica officinalis* L.	In alcoholic beverages only.
Vervain, European	*Verbena officinalis* L.	Do.
Vetiver	*Vetiveria zizanioides* Stapf.	Do.
Violet, Swiss	*Viola calcarata* L.	
Walnut husks (hulls), leaves, and green nuts.	*Juglans nigra* L. or *J. regia* L.	
Woodruff, sweet	*Asperula odorata* L.	Do.
Yarrow	*Achillea millefolium* L.	In beverages only; finished beverage thujone free.[1]
Yerba santa	*Eriodictyon californicum* (Hook. et Arn.) Torr.	
Yucca, Joshua-tree	*Yucca brevifolia* Engelm.	
Yucca, Mohave	*Yucca schidigera* Roezl ex Ortgies (*Y. mohavensis* Sarg.).	

[1] As determined by using the method (or, in other than alcoholic beverages, a suitable adaptation thereof) in sec. 9.091, "Official Methods of Analysis of the Association of Official Agricultural Chemists," 10th Edition (1965).

§ 172.515 Synthetic flavoring substances and adjuvants.

Synthetic flavoring substances and adjuvants may be safely used in food in accordance with the following conditions.

(a) They are used in the minimum quantity required to produce their intended effect, and otherwise in accordance with all the principles of good manufacturing practice.

(b) They consist of one or more of the following, used alone or in combination with flavoring substances and adjuvants generally recognized as safe in food, prior-sanctioned for such use, or regulated by an appropriate section in this part.

Acetal; acetaldehyde diethyl acetal.
Acetaldehyde phenethyl propyl acetal.
Acetanisole; 4'-methoxyacetophenone.
Acetophenone; methyl phenyl ketone.
Adipic acid; 1,4-butanedicarboxylic acid.
Allyl anthranilate.
Allyl butyrate.
Allyl cinnamate.
Allyl cyclohexaneacetate.
Allyl cyclohexanebutyrate.
Allyl cyclohexanehexanoate.
Allyl cyclohexanepropionate.
Allyl cyclohexanevalerate.
Allyl disulfide.
Allyl 2-ethylbutyrate.
Allyl hexanoate; allyl caproate.
Allyl α-ionone; 1-(2,6,6-trimethyl-2-cyclohexen-1-yl)-1,6-heptadiene-3-one.
Allyl isothiocyanate; mustard oil.
Allyl isovalerate.
Allyl mercaptan; 2-propene-1-thiol.
Allyl nonanoate.
Allyl octanoate.
Allyl phenoxyacetate.
Allyl phenylacetate.
Allyl propionate.
Allyl sorbate; allyl 2,4-hexadienoate.
Allyl sulfide.
Allyl tiglate; allyl *trans*-2-methyl-2-butenoate.
Allyl 10-undecenoate.
Ammonium isovalerate.
Ammonium sulfide.
Amyl alcohol; pentyl alcohol.
Amyl butyrate.
α-Amylcinnamaldehyde.
α-Amylcinnamaldehyde dimethyl acetal.
α-Amylcinnamyl acetate.
α-Amylcinnamyl alcohol.
α-Amylcinnamyl formate.
α-Amylcinnamyl isovalerate.
Amyl formate.
Amyl heptanoate.
Amyl hexanoate.
Amyl octanoate.
Anisole; methoxybenzene.
Anisyl acetate.
Anisyl alcohol; *p*-methoxybenzyl alcohol.
Anisyl butyrate
Anisyl formate.
Anisyl phenylacetate.
Anisyl propionate.
Beechwood creosote.
Benzaldehyde dimethyl acetal.
Benzaldehyde glyceryl acetal; 2-phenyl-*m*-dioxan-5-ol.
Benzaldehyde propylene glycol acetal; 4-methyl-2-phenyl-*m*-dioxolane.
Benzenethiol; thiophenol.
Benzoin; 2-hydroxy-2-phenylacetophenone.
Benzophenone; diphenylketone.
Benzyl acetate.
Benzyl acetoacetate.
Benzyl alcohol.
Benzyl benzoate.
Benzyl butyl ether.
Benzyl butyrate.
Benzyl cinnamate.
Benzyl 2,3-dimethylcrotonate; benzyl methyl tiglate.
Benzyl disulfide; dibenzyl disulfide.
Benzyl ethyl ether.
Benzyl formate.
3-Benzyl-4-heptanone; benzyl dipropyl ketone.
Benzyl isobutyrate.

Benzyl isovalerate.
Benzyl mercaptan; α-toluenethiol.
Benzyl methoxyethyl acetal; acetaldehyde benzyl β-methoxyethyl acetal.
Benzyl phenylacetate.
Benzyl propionate.
Benzyl salicylate.
Birch tar oil.
Borneol; *d*-camphanol.
Bornyl acetate.
Bornyl formate.
Bornyl isovalerate.
Bornyl valerate.
β-Bourbonene; 1,2,3,3a,3bβ,4,5,6,6aβ,6bα-decahydro-1α-isopropyl-3a$_a$-methyl - 6-methylene-cyclobuta [1,2:3,4] dicyclopentene.
2-Butanone; methyl ethyl ketone.
Butter acids.
Butter esters.
Butter starter distillate.
Butyl acetate.
Butyl acetoacetate.
Butyl alcohol; 1-butanol.
Butyl anthranilate.
Butyl butyrate.
Butyl butyryllactate; lactic acid, butyl ester, butyrate.
α-Butylcinnamaldehyde.
Butyl cinnamate.
Butyl 2-decenoate.
Butyl ethyl malonate.
Butyl formate.
Butyl heptanoate.
Butyl hexanoate.
Butyl *p*-hydroxybenzoate.
Butyl isobutyrate.
Butyl isovalerate.
Butyl lactate.
Butyl laurate.
Butyl levulinate.
Butyl phenylacetate.
Butyl propionate.
Butyl stearate.
Butyl sulfide.
Butyl 10-undecenoate.
Butyl valerate.
Butyraldehyde.
Cadinene.
Camphene; 2,2 - dimethyl - 3 - methylenenorbornane.
d-Camphor.
Carvacrol; 2-*p*-cymenol.
Carvacryl ethyl ether; 2-ethoxy-*p*-cymene.
Carveol; *p*-mentha-6,8-dien-2-ol.
4-Carvomenthenol; 1-*p*-menthen-4-ol; 4-terpinenol.
cis Carvone oxide; 1,6-epoxy-*p*-menth-8-en-2-one.
Carvyl acetate.
Carvyl propionate.
β-Caryophyllene.
Caryophyllene alcohol.
Caryophyllene alcohol acetate.
β-Caryophyllene oxide; 4-12,12-trimethyl-9-methylene-5-oxatricylo [8.2.0.0 ^{4,6}] dodecane.
Cedarwood oil alcohols.
Cedarwood oil terpenes.
1,4-Cineole.
Cinnamaldehyde ethylene glycol acetal.
Cinnamic acid.
Cinnamyl acetate.
Cinnamyl alcohol; 3-phenyl-2-propen-1-ol.
Cinnamyl anthranilate.
Cinnamyl benzoate.
Cinnamyl butyrate.
Cinnamyl cinnamate.
Cinnamyl formate.
Cinnamyl isobutyrate.
Cinnamyl isovalerate.
Cinnamyl phenylacetate.
Cinnamyl propionate.
Citral diethyl acetal; 3,7-dimethyl-2,6-octadienal diethyl acetal.
Citral dimethyl acetal; 3,7-dimethyl-2,6-octadienal dimethyl acetal.
Citral propylene glycol acetal.
Citronellal; 3,7-dimethyl-6-octenal; rhodinal.
Citronellol; 3,7-dimethyl-6-octen-1-ol; *d*-citronellol.
Citronelloxyacetaldehyde.
Citronellyl acetate.
Citronellyl butyrate.
Citronellyl formate.
Citronellyl isobutyrate.
Citronellyl phenylacetate.
Citronellyl propionate.
Citronellyl valerate.
p-Cresol.
Cuminaldehyde; cuminal; *p*-isopropyl benzaldehyde.
Cyclohexaneacetic acid.
Cyclohexaneethyl acetate.
Cyclohexyl acetate.
Cyclohexyl anthranilate.
Cyclohexyl butyrate.
Cyclohexyl cinnamate.
Cyclohexyl formate.
Cyclohexyl isovalerate.
Cyclohexyl propionate.
p-Cymene.
γ-Decalactone; 4-hydroxy-decanoic acid, γ-lactone.
δ-Decalactone; 5-hydroxy-decanoic acid, δ-lactone.
Decanal dimethyl acetal.
1-Decanol; decylic alcohol.
2-Decenal.
3-Decen-2-one; heptylidene acetone.
Decyl actate.
Decyl butyrate.
Decyl propionate.
Dibenzyl ether.
4,4-Dibutyl-γ-butyrolactone; 4,4-dibutyl-4-hydroxy-butyric acid, γ-lactone.
Dibutyl sebacate.
Diethyl malate.
Diethyl malonate; ethyl malonate.
Diethyl sebacate.
Diethyl succinate.
Diethyl tartrate.
2,5-Diethyltetrahydrofuran.
Dihydrocarveol; 6-*p*-menthen-2-ol; 6-methyl-3-isopropenylcyclohexanol.
Dihydrocarvone.
Dihydrocarvyl acetate.
m-Dimethoxybenzene.
p-Dimethoxybenzene; dimethyl hydroquinone.
2,4-Dimethylacetophenone.
α,α-Dimethylbenzyl isobutyrate; phenyldimethylcarbinyl isobutyrate.
2,6-Dimethyl-5-heptenal.
2,6-Dimethyl octanal; isodecylaldehyde.
3,7-Dimethyl-1-octanol; tetrahydrogeraniol.
α,α-Dimethylphenethyl acetate; benzylpropyl acetate; benzyldimethylcarbinyl acetate.
α,α-Dimethylphenethyl alcohol; dimethylbenzyl carbinol.
α,α-Dimethylphenethyl butyrate; benzyldimethylcarbinyl butyrate.
α,α-Dimethylphenethyl formate; benzyldimethylcarbinyl formate.
Dimethyl succinate.
1,3-Diphenyl-2-propanone; dibenzyl ketone.
delta-Dodecalactone; 5-hydroxydodecanoic acid, deltalactone.
γ-Dodecalactone; 4-hydroxydodecanoic acid γ-lactone.
2-Dodecenal.
Estragole.
p-Ethoxybenzaldehyde.
Ethyl acetoacetate.
Ethyl 2-acetyl-3-phenylpropionate; ethylbenzyl acetoacetate.
Ethyl aconitate, mixed esters.
Ethyl acrylate.
Ethyl *p*-anisate.
Ethyl anthranilate.
Ethyl benzoate.
Ethyl benzoylacetate.
α-Ethylbenzyl butyrate; α-phenylpropyl butyrate.
Ethyl brassylate; tridecanedioic acid cyclic ethylene glycol diester; cyclo 1,13-ethylenedioxytridecan-1,13-dione.
2-Ethylbutyl acetate.
2-Ethylbutyraldehyde.
2-Ethylbutyric acid.
Ethyl cinnamate.
Ethyl crotonate; *trans*-2-butenoic acid ethyl-ester.
Ethyl cyclohexanepropionate.
Ethyl decanoate.
Ethyl formate.
2-Ethylfuran.
Ethyl 2-furanpropionate.
4-Ethylguaiacol; 4-ethyl-2-methoxyphenol.
Ethyl heptanoate.
2-Ethyl-2-heptenal; 2-ethyl-3-butylacrolein.
Ethyl hexanoate.
Ethyl isobutyrate.
Ethyl isovalerate.
Ethyl lactate.
Ethyl laurate.
Ethyl levulinate.
Ethyl maltol; 2-ethyl-3-hydroxy-4H-pyran-4-one.
Ethyl 2-methylbutyrate.
Ethyl myristate.
Ethyl nitrite.
Ethyl nonanoate.
Ethyl 2-nonynoate; ethyl octyne carbonate.
Ethyl octanoate.
Ethyl oleate.
Ethyl phenylacetate.
Ethyl 4-phenylbutyrate.
Ethyl 3-phenylglycidate.
Ethyl 3-phenylpropionate; ethyl hydrocinnamate.
Ethyl propionate.
Ethyl pyruvate.
Ethyl salicylate.
Ethyl sorbate; ethyl 2,4-hexadienoate.
Ethyl tiglate; ethyl *trans*-2-methyl-2-butenoate.
Ethyl undecanoate.
Ethyl 10-undecenoate.
Ethyl valerate.
Eucalpytol; 1,8-epoxy-*p*-menthane; cineole.
Eugenyl acetate.
Eugenyl benzoate.
Eugenyl formate.
Eugenyl methyl ether; 4-allylveratrole; methyl eugenol.
Farnesol; 3,7,11-trimethyl-2,6,10-dodecatrien-1-ol.
d-Fenchone; *d*-1,3,3-trimethyl-2-norbornanone.
Fenchyl alcohol; 1,3,3-trimethyl-2-norbornanol.
Formic acid
(2-Furyl)-2-propanone; furyl acetone.
1-Furyl-2-propanone; furyl acetone.
Fusel oil, refined (mixed amyl alcohols).
Geranyl acetoacetate; *trans*-3,7-dimethyl-2,6-octadien-1-yl acetoacetate.
Geranyl acetone; 6,10-dimethyl-5,9-undecadien-2-one.
Geranyl benzoate.
Geranyl butyrate.
Geranyl formate.
Geranyl hexanoate
Geranyl isobutyrate.
Geranyl isovalerate.
Geranyl phenylacetate.
Geranyl propionate.
Glucose pentaacetate.
Glyceryl monooleate.
Guaiacol; *o*-methoxyphenol.
Guaiacyl acetate; *o*-methoxyphenyl acetate.
Guaiacyl phenylacetate.
Gualene; 1,4-dimethyl-7-isopropenyl-Δ9, 10-octahydroazulene.
Guaiol acetate; 1,4-dimethyl-7-(α-hydroxyisopropyl)-Δ9,10-octahydroazulene acetate.
γ-Heptalactone; 4-hydroxyheptanoic acid, γ-lactone.
Heptanal; enanthaldehyde.
Heptanal dimethyl acetal.
Heptanal 1,2-glyceryl acetal.
2,3-Heptanedione; acetyl valeryl.
3-Heptanol.
2-Heptanone; methyl amyl ketone.

3-Heptanone; ethyl butyl ketone.
4-Heptanone; dipropyl ketone.
cis-4-Heptenal; *cis*-4-hepten-1-al.
Heptyl acetate.
Heptyl alcohol; enanthic alcohol.
Heptyl butyrate.
Heptyl cinnamate.
Heptyl formate.
Heptyl isobutyrate.
Heptyl octanoate.
1-Hexadecanol; cetyl alcohol.
ω-6-Hexadecenlactone; 16-hydroxy-6-hexadecenoic acid, ω-lactone; ambrettolide.
γ-Hexalactone; 4-hydroxyhexanoic acid, γ-lactone; tonkalide.
Hexanal; caproic aldehyde.
2,3-Hexanedione; acetyl butyryl.
Hexanoic acid; caproic acid.
2-Hexenal.
2-Hexen-1-ol.
3-Hexen-1-ol; leaf alcohol.
2-Hexen-1-yl acetate.
3-Hexenyl isovalerate.
3-Hexenyl 2-methylbutyrate.
3-Hexenyl phenylacetate; cis-3-hexenyl phenylacetate.
Hexyl acetate.
2-Hexyl-4-acetoxytetrahydrofuran.
Hexyl alcohol.
Hexyl butyrate.
α-Hexylcinnamaldehyde.
Hexyl formate.
Hexyl hexanoate.
2-Hexylidene cyclopentanone.
Hexyl isovaleratel.
Hexyl 2-methylbutyrate.
Hexyl octanoate.
Hexyl phenylacetate; *n*-hexyl phenylacetate.
Hexyl propionate.
Hydroxycitronellal; 3,7-dimethyl-7-hydroxyoctanal.
Hydroxycitronellal diethyl acetal.
Hydroxycitronellal dimethyl acetal.
Hydroxycitronellol; 3,7-dimethyl-1,7-octanediol.
N-(4-Hydroxy-3-methoxybenzyl) -nonanamide; pelargonyl vanillylamide.
5-Hydroxy-4-octanone; butyroin.
4-(*p*-Hydroxyphenyl)-2-butanone; *p*-hydroxybenzyl acetone.
Indole.
α-Ionone; 4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one.
β-Ionone; 4-(2,6,6-trimethyl-1-cyclohexen-1-yl)-3-buten-2-one.
ε-Irone; 4-(2,5,6,6-tetramethyl-2-cyclohexene-1-yl)-3-buten-2-one; 6-methylionone.
Isoamyl acetate.
Isoamyl acetoacetate.
Isoamyl alcohol; isopentyl alcohol; 3-methyl-1-butanol.
Isoamyl benzoate.
Isoamyl butyrate.
Isoamyl cinnamate.
Isoamyl formate.
Isoamyl 2-furanbutyrate; α-isoamyl furfurylpropionate.
Isoamyl 2-furanpropionate; α-isoamyl furfurylacetate.
Isoamyl hexanoate.
Isoamyl isobutyrate.
Isoamyl isovalerate.
Isoamyl laurate.
Isoamyl-2-methylbutyrate; isopentyl-2-methylbutyrate.
Isoamyl nonanoate.
Isoamyl octanoate.
Isoamyl phenylacetate.
Isoamyl propionate.
Isoamyl pyruvate.
Isoamyl salicylate.
Isoborneol.
Isobornyl acetate.
Isobornyl formate.
Isobornyl isovalerate.
Isobornyl propionate.
Isobutyl acetate.
Isobutyl acetoacetate.
Isobutyl alcohol.
Isobutyl angelate; isobutyl *cis*-2-methyl-2-butenoate.
Isobutyl anthranilate.
Isobutyl benzoate.
Isobutyl butyrate.
Isobutyl cinnamate.
Isobutyl formate.
Isobutyl 2-furanpropionate.
Isobutyl heptanoate.
Isobutyl hexanoate.
Isobutyl isobutyrate.
α-Isobutylphenethyl alcohol; isobutyl benzyl carbinol; 4-methyl-1-phenyl-2-pentanol.
Isobutyl phenylacetate.
Isobutyl propionate.
Isobutyl salicylate.
Isobutyraldehyde.
Isobutyric acid.
Isoeugenol; 2-methoxy-4-propenylphenol.
Isoeugenyl acetate.
Isoeugenyl benzyl ether; benzyl isoeugenol.
Isoeugenyl ethyl ether; 2-ethoxy-5-propenylanisole; ethyl isoeugenol.
Isoeugenyl formate.
Isoeugenyl methyl ether; 4-propenylveratrole; methyl isoeugenol.
Isoeugenyl phenylacetate.
Isojasmone; mixture of 2-hexylidenecyclopentanone and 2-hexyl-2-cyclopenten-1-one.
ε-Isomethylionone; 4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-methyl-3-buten-2-one; methyl γ-ionone.
Isopropyl acetate.
p-Isopropylacetophenone.
Isopropyl alcohol; isopropanol.
Isopropyl benzoate.
p-Isopropylbenzyl alcohol; cuminic alcohol; *p*-cymen-7-ol.
Isopropyl butyrate.
Isopropyl cinnamate.
Isopropyl formate.
Isopropyl hexanoate.
Isopropyl isobutyrate.
Isopropyl isovalerate.
p-Isopropylphenylacetaldehyde; *p*-cymen-7-carboxaldehyde.
Isopropyl phenylacetate.
3-(*p*-Isopropylphenyl)-propionaldehyde; *p*-isopropylhydrocinnamaldehyde; cuminyl acetaldehyde.
Isopropyl propionate.
Isopulegol; *p*-menth-8-en-3-ol.
Isopulegone; *p*-menth-8-en-3-one.
Isopulegyl acetate.
Isoquinoline.
Isovaleric acid.
cis-Jasmone; 3-methyl-2-(2-pentenyl)-2-cyclopenten-1-one.
Lauric aldehyde; dodecanal.
Lauryl acetate.
Lauryl alcohol; 1-dodecanol.
Lepidine; 4-methylquinoline.
Levulinic acid.
Linalool oxide; *cis*- and *trans*-2-vinyl-2-methyl-5-(1'-hydroxy-1'-methylethyl) tetrahydrofuran.
Linalyl anthranilate; 3,7-dimethyl-1, 6-octadien-3-yl anthranilate.
Linalyl benzoate.
Linalyl butyrate.
Linalyl cinnamate.
Linalyl formate.
Linalyl hexanoate.
Linalyl isobutyrate.
Linalyl isovalerate.
Linalyl octanoate.
Linalyl propionate.
Maltol; 3-hydroxy-2-methyl-4H-pyran-4-one.
Menthadienol; *p*-mentha-1,8(10)-dien-9-ol.
p-Mentha-1,8-dien-7-ol; perillyl alcohol.
Menthadienyl acetate; *p*-mentha-1,8(10)-dien-9-yl acetate.
p-Menth-3-en-1-ol.
1-*p*-Menthen-9-yl acetate; *p*-menth-1-en-9-yl acetate.
Menthol; 2-isopropyl-5-methylcyclohexanol.
Menthone; *p*-menthan-3-one.
Menthyl acetate; *p*-menth-3-yl acetate.
Menthyl isovalerate; *p*-menth-3-yl isovalerate.
o-Methoxybenzaldehyde.
p-Methoxybenzaldehyde; *p*-anisaldehyde.
o-Methoxycinnamaldehyde.
2-Methoxy-4-methylphenol; 4-methylguaiacol; 2-methoxy-*p*-cresol.
4-(*p*-Methoxyphenyl)-2-butanone; anisyl acetone.
1-(4-Methoxyphenyl)-4-methyl-1-penten-3-one; methoxystyryl isopropyl ketone.
1-(*p*-Methoxyphenyl)-1-penten-3-one; α-methylanisylidene acetone; ethone.
1-(*p*-Methoxyphenyl)-2-propanone; anisylmethyl ketone; anisic ketone.
2-Methoxy-4-vinylphenol; *p*-vinylguaiacol.
Methyl acetate.
4'-Methylacetophenone; *p*-methylacetophenone; methyl *p*-tolyl ketone.
2-Methoxy-4-vinylphenol; *p*-vinylguaiacol.
1-yl butyrate.
Methyl anisate.
o-Methylanisole; *o*-cresyl methyl ether.
p-Methylanisole; *p*-cresyl methyl ether; *p*-methoxytoluene.
Methyl benzoate.
Methylbenzyl acetate, mixed *o*-,*m*-,*p*-.
α-Methylbenzyl acetate; styralyl acetate.
α-Methylbenzyl alcohol; styralyl alcohol.
α-Methylbenzyl butyrate; styralyl butyrate.
α-Methylbenzyl isobutyrate; styralyl isobutyrate.
α-Methylbenzyl formate; styralyl formate.
α-Methylbenzyl propionate; styralyl propionate.
2-Methylbutyl isovalerate.
Methyl *p*-*tert*-butylphenylacetate.
2-Methylbutyraldehyde; methyl ethyl acetaldehyde.
3-Methylbutyraldehyde; isovaleraldehyde.
Methyl butyrate.
2-Methylbutyric acid.
α-Methylcinnamaldehyde.
p-Methylcinnamaldehyde.
Methyl cinnamate.
2-Methyl-1,3-cyclohexadiene.
Methylcyclopentenolone; 3-methylcyclopentane-1,2-dione.
Methyl disulfide; dimethyl disulfide.
Methyl ester of rosin, partially hydrogenated (as defined in § 172.615); methyl dihydroabietate.
Methyl heptanoate.
2-Methylheptanoic acid.
6-Methyl-5-hepten-2-one.
Methyl hexanoate.
Methyl 2-hexanoate.
Methyl *p*-hydroxybenzoate; methylparaben.
Methyl α-ionone; 5-(2,6,6-trimethyl-2-cyclohexen-1-yl)-4-penten-3-one.
Methyl β-ionone; 5,(2,6,6-trimethyl-3-cyclohexen-1-yl)-4-penten-3-one.
Methyl Δ-ionone; 5-(2,6,6-trimethyl-3-cyclohexen-1-yl)-4-penten-3-one.
Methyl isobutyrate.
2-Methyl-3-(*p*-isopropylphenyl)-propionaldehyde; α-methyl-*p*-isopropylhydrocinnamaldehyde; cyclamen aldehyde.
Methyl isovalerate.
Methyl laurate.
Methyl mercaptan; methanethiol.
Methyl *o*-methoxybenzoate.
Methyl *N*-methylanthranilate; dimethyl anthranilate.
Methyl 2-methylbutyrate.
Methyl 2-methylthiopropionate.
Methyl 4-methylvalerate.
Methyl myristate.
Methyl β-naphthyl ketone; 2'-acetonaphthone.
Methyl nonanoate.
Methyl 2-nonenoate.
Methyl 2-nonynoate; methyloctyne carbonate.
2-Methyloctanal; methyl hexyl acetaldehyde.
Methyl octanoate.
Methyl 2-octynoate; methyl heptine carbonate.

4-Methyl-2,3-pentanedione; acetyl isobutyryl.
4-Methyl-2-pentanone; methyl isobutyl ketone.
β-Methylphenethyl alcohol; hydratrophyl alcohol.
Methyl phenylacetate.
3-Methyl-4-phenyl-3-butene-2-one.
2-Methyl-4-phenyl-2-butyl acetate; dimethylphenylethyl carbinyl acetate.
2-Methyl-4-phenyl-2-butyl isobutyrate; dimethylphenyl-ethylcarbinyl isobutyrate.
3-Methyl-2-phenylbutyraldehyde; α-isopropyl phenylacetaldehyde.
Methyl 4-phenylbutyrate.
4-Methyl-1-phenyl-2-pentanone; benzyl isobutyl ketone.
Methyl 3-phenylpropionate; methyl hydrocinnamate.
Methyl propionate.
3-Methyl-5-propyl-2-cyclohexen-1-one.
Methyl sulfide.
3-Methylthiopropionaldehyde; methional.
2-Methyl-3-tolylpropionaldehyde, mixed *o*-, *m*-, *p*-.
2-Methylundecanal; methyl nonyl acetaldehyde.
Methyl 9-undecenoate.
Methyl 2-undecynoate; methyl decyne carbonate.
Methyl valerate.
2-Methylvaleric acid.
Myrcene; 7-methyl-3-methylene-1,6-octadiene.
Myristaldehyde; tetradecanal.
d-Neomenthol; 2-isobutyl-5-methylcyclohexanol.
Nerol; *cis*-3,7-dimethyl-2,6-octadien-1-ol.
Nerolidol; 3,7,11-trimethyl-1,6,10-dodecatrien-3-ol.
Neryl acetate.
Neryl butyrate.
Neryl formate.
Neryl isobutyrate.
Neryl isovalerate.
Neryl propionate.
2,6-Nonadien-1-ol.
γ-Nonalactone; 4-hydroxynonanoic acid, γ-lactone; aldehyde C-18.
Nonanal; pelargonic aldehyde.
1,3-Nonanediol acetate, mixed esters.
Nonanoic acid; pelargonic acid.
2-Nonanone; methylheptyl ketone.
3-Nonanon-1-yl acetate; 1-hydroxy-3-nonanone acetate.
Nonyl acetate.
Nonyl alcohol; 1-nonanol.
Nonyl octanoate.
Nonyl isovalerate.
Nootkatone; 5,6-dimethyl-8-isopropenyl-bicyclo[4,4,0]-dec-1-en-3-one.
Ocimene; *trans*-β-ocimene; 3,7-dimethyl-1,3,6-octatriene.
γ-Octalactone; 4-hydroxyoctanoic acid, γ-lactone.
Octanal; caprylaldehyde.
Octanal dimethyl acetal.
Octanoic acid; caprylic acid.
1-Octanol; octyl alcohol.
2-Octanol.
3-Octanol.
2-Octanone; methyl hexyl ketone.
3-Octanone; ethyl amyl ketone.
3-Octanon-1-ol.
1-Octen-3-ol; amyl vinyl carbinol.
1-Octen-3-yl acetate.
Octyl acetate.
3-Octyl acetate.
Octyl butyrate.
Octyl formate.
Octyl heptanoate.
Octyl isobutyrate.
Octyl isovalerate.
Octyl octanoate.
Octyl phenylacetate.
Octyl propionate.
ω-Pentadecalactone; 15-hydroxypentadecanoic acid, ω-lactone; pentadecanolide; angelica lactone.
2,3-Pentanedione; acetyl propionyl.
2-Pentanone; methyl propyl ketone.
4-Pentenoic acid.
1-Penten-3-ol.
Perillaldehyde; 4-isopropenyl-1-cyclohexene-1-carboxaldehyde; *p*-mentha-1,8-dien-7-al.
Perillyl acetate; *p*-mentha-1,8-dien-7-yl acetate.
α-Phellandrene; *o*-mentha-1,5-diene.
Phenethyl acetate.
Phenethyl alcohol; β-phenylethyl alcohol.
Phenethyl anthranilate.
Phenethyl benzoate.
Phenethyl butyrate.
Phenethyl cinnamate.
Phenethyl formate.
Phenethyl isobutyrate.
Phenethyl isovalerate.
Phenethyl 2-methylbutyrate.
Phenethyl phenylacetate.
Phenethyl propionate.
Phenethyl salicylate.
Phenethyl senecioate; phenethyl 3,3-dimethylacrylate.
Phenethyl tiglate.
Phenoxyacetic acid.
2-Phenoxyethyl isobutyrate.
Phenylacetaldehyde; α-toluic aldehyde.
Phenylacetaldehyde 2,3-butylene glycol acetal.
Phenylacetaldehyde dimethyl acetal.
Phenylacetaldehyde glyceryl acetal.
Phenylacetic acid; α-toluic acid.
4-Phenyl-2-butanol; phenylethyl methyl carbinol.
4-Phenyl-3-buten-2-ol; methyl styryl carbinol.
4-Phenyl-3-buten-2-one.
4-Phenyl-2-butyl acetate; phenylethyl methyl carbinyl acetate.
1-Phenyl-3-methyl-3-pentanol; phenylethyl methyl ethyl carbinol.
1-Phenyl-1-propanol; phenylethyl carbinol.
3-Phenyl-1-propanol; hydrocinnamyl alcohol.
2-Phenylpropionaldehyde; hydratropaldehyde.
3-Phenylpropionaldehyde; hydrocinnamaldehyde.
2-Phenylpropionaldehyde dimethyl acetal; hydratropic aldehyde dimethyl acetal.
3-Phenylpropionic acid; hydrocinnamic acid.
3-Phenylpropyl acetate.
2-Phenylpropyl butyrate.
3-Phenylpropyl cinnamate.
3-Phenylpropyl formate.
3-Phenylpropyl hexanoate.
2-Phenylpropyl isobutyrate.
3-Phenylpropyl isobutyrate.
3-Phenylpropyl isovalerate.
3-Phenylpropyl propionate.
2-(3-Phenylpropyl)-tetrahydrofura..
α-Pinene; 2-pinene.
β-Pinene; 2(10)-pinene.
Pine tar oil.
Pinocarveol; 2(10)-pinen-3-ol.
Piperidine.
Piperine.
d-Piperitone; *p*-menth-1-en-3-one.
Piperitenone; *p*-mentha-1,4(8)-dien-3-one.
Piperitenone oxide; 1,2-epoxy-*p*-menth-4(8)-en-3-one.
Piperonyl acetate; heliotropyl acetate.
Piperonyl isobutyrate.
Polylimonene.
Polysorbate 20; polyoxyethylene (20) sorbitan monolaurate.
Polysorbate 60; polyoxyethylene (20) sorbitan monostereate.
Polysorbate 80; polyoxyethylene (20) sorbitan monooleate.
Potassium acetate.
Propenylguaethol; 6-ethoxy-*m*-anol.
Propionaldehyde.
Propyl acetate.
Propyl alcohol; 1-propanol.
p-Propyl anisole; dihydroanethole.
Propyl benzoate.
Propyl butyrate.
Propyl cinnamate.
Propyl disulfide.
Propyl formate.
Propyl 2-furanacrylate.
Propyl heptanoate.
Propyl hexanoate.
Propyl *p*-hydroxybenzoate; propylparaben.
3-Propylidenephthalide.
Propyl isobutyrate.
Propyl isovalerate.
Propyl mercaptan.
α-Propylphenethyl alcohol.
Propyl phenylacetate.
Propyl propionate.
Pulegone; *p*-menth-4(8)-en-3-one.
Pyridine.
Pyroligneous acid extract.
Pyruvaldehyde.
Pyruvic acid.
Rhodinol; 3,7-dimethyl-7-octen-1-ol; *l*-citronellol.
Rhodinyl acetate.
Rhodinyl butyrate.
Rhodinyl formate.
Rhodinyl isobutyrate.
Rhodinyl isovalerate.
Rhodinyl phenylacetate.
Rhodinyl propionate.
Rum ether; ethyl oxyhydrate.
Salicylaldehyde.
Santalol, α and β.
Santalyl acetate.
Santalyl phenylacetate.
Skatole.
Sorbitan monostearate.
Styrene.
Sucrose octaacetate.
α-Terpinene.
γ-Terpinene.
α-Terpineol; *p*-menth-1-en-8-ol.
β-Terpineol.
Terpinolene; *p*-menth-1,4(8)-diene.
Terpinyl acetate.
Terpinyl anthranilate.
Terpinyl butyrate.
Terpinyl cinnamate.
Terpinyl formate.
Terpinyl isobutyrate.
Terpinyl isovalerate.
Terpinyl propionate.
Tetrahydrofurfuryl acetate.
Tetrahydrofurfuryl alcohol.
Tetrahydrofurfuryl butyrate.
Tetrahydrofurfuryl propionate.
Tetrahydro-pseudo-ionone; 6,10-dimethyl-9-undecen-2-one.
Tetrahydrolinalool; 3,7-dimethyloctan-3-ol.
Tetramethyl ethylcyclohexenone; mixture of 5-ethyl-2,3,4,5-tetramethyl-2-cyclohexen-1-one and 5-ethyl-3,4,5,6-tetramethyl-2-cyclohexen-1-one.
2-Thienyl mercaptan; 2-thienylthiol.
Thymol.
Tolualdehyde glyceryl acetal, mixed *o*, *m*, *p*.
Tolualdehydes, mixed *o*, *m*, *p*.
p-Tolylacetaldehyde.
o-Tolyl acetate; *o*-cresyl acetate.
p-Tolyl acetate; *p*-cresyl acetate.
4-(*p*-Tolyl)-2-butanone; *p*-methylbenzylacetone.
p-Tolyl isobutyrate.
p-Tolyl laurate.
p-Tolyl phenylacetate.
2-(*p*-Tolyl)-propionaldehyde; *p*-methylhydratropic aldehyde.
Tributyl acetylcitrate.
2-Tridecenal.
2,3-Undecadione; acetyl nonyryl.
γ-Undecalactone; 4-hydroxyundecanoic acid γ-lactone; peach aldehyde; aldehyde C-14.
Undecenal.
2-Undecanone; methyl nonyl ketone.
9-Undecenal; undecenoic aldehyde.
10-Undecenal.
Undecen-1-ol; undecylenic alcohol.
10-Undecen-1-yl acetate.
Undecyl alcohol.
Valeraldehyde; pentanal.
Valeric acid; pentanoic acid.
Vanillin acetate; acetyl vanillin.

Veratraldehyde.
Verbenol; 2-pinen-4-ol.
Zingerone; 4-(4-hydroxy-3-methoxyphenyl)-2-butanone.

(c) α-Decalactone and α-dodecalactone when used separately or in combination in oleomargarine are used at levels not to exceed 10 parts per million and 20 parts per million, respectively, in accordance with § 166.110 of this chapter.

(d) BHA (butylated hydroxyanisole) may be used as an antioxidant in flavoring substances whereby the additive does not exceed 0.5 percent of the essential (volatile) oil content of the flavoring substance.

§ 172.520 Cocoa with dioctyl sodium sulfosuccinate for manufacturing.

The food additive "cocoa with dioctyl sodium sulfosuccinate for manufacturing," conforming to § 163.117 of this chapter and § 172.810, is used or intended for use as a flavoring substance in dry beverage mixes whereby the amount of dioctyl sodium sulfosuccinate does not exceed 75 parts per million of the finished beverage. The labeling of the dry beverage mix shall bear adequate directions to assure use in compliance with this section.

§ 172.530 Disodium guanylate.

Disodium guanylate may be safely used as a flavor enhancer in foods, at a level not in excess of that reasonably required to produce the intended effect.

§ 172.535 Disodium inosinate.

The food additive disodium inosinate may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the disodium salt of inosinic acid, manufactured and purified so as to contain no more than 150 parts per million of soluble barium in the compound disodium inosinate with seven and one-half molecules of water of crystallization.

(b) The food additive is used as a flavoring adjuvant in food.

§ 172.560 Modified hop extract.

The food additive modified hop extract may be safely used in beer in accordance with the following prescribed conditions:

(a) The food additive is used or intended for use as a flavoring agent in the brewing of beer.

(b) The food additive is manufactured by one of the following processes:

(1) The additive is manufactured from a hexane extract of hops by simultaneous isomerization and selective reduction in an alkaline aqueous medium with sodium borohydride, whereby the additive meets the following specifications:

(i) A solution of the food additive solids is made up in approximately 0.012 *n* alkaline methyl alcohol (6 milliliters of 1 *n* sodium hydroxide diluted to 500 milliliters with methyl alcohol) to show an absorbance at 253 millimicrons of 0.6 to 0.9 per centimeter. (This absorbance is obtained by approximately 0.03 milligram solids permilliliter.) The ultraviolet absorption spectrum of this solution exhibits the following characteristics: An absorption peak at 253 millimicrons; no absorption peak at 325 to 330 millimicrons; the absorbance at 268 millimicrons does not exceed the absorbance at 272 millimicrons.

(ii) The boron content of the food additive does not exceed 310 parts per million (0.0310 percent), calculated as boron.

(2) The additive is manufactured from hops by a sequence of extractions and fractionations, using benzene, light petroleum spirits, and methyl alcohol as solvents, followed by isomerization by potassium carbonate treatment. Residues of solvents in the modified hop extract shall not exceed 1.0 part per million of benzene, 1.0 part per million of light petroleum spirits, and 250 parts per million of methyl alcohol. The light petroleum spirits and benzene solvents shall comply with the specifications in § 172.250 except that the boiling point range for light petroleum spirits is 150° F—300° F.

(3) The additive is manufactured from hops by a sequence of extractions and fractionations, using methylene chloride, hexane, and methyl alcohol as solvents, followed by isomerization by sodium hydroxide treatment. Residues of the solvents in the modified hop extract shall not exceed 5 parts per million of methylene chloride, 25 parts per million of hexane, and 100 parts per million of methyl alcohol.

(4) The additive is manufactured from hops by a sequence of extractions and fractionations, using benzene, light petroleum spirits, methyl alcohol, *n*-butyl alcohol, and ethyl acetate as solvents, followed by isomerization by potassium carbonate treatment. Residues of solvents in the modified hop extract shall not exceed 1.0 part per million of benzene, 1.0 part per million of light petroleum spirits, 50 parts per million of methyl alcohol, 50 parts per million of *n*-butyl alcohol, and 1 part per million of ethyl acetate. The light petroleum spirits and benzene solvents shall comply with the specifications in § 172.250 except that the boiling point range for light petroleum spirits is 150° F to 300° F.

(5) The additive is manufactured from hops by an initial extraction and fractionation using one or more of the following solvents: Ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, trichloroethylene, and water; followed by isomerization by calcium chloride or magnesium chloride treatment in ethylene dichloride, methylene chloride, or trichloroethylene and a further sequence of extractions and fractionations using one or more of the solvents set forth in this paragraph. Residues of the solvents in the modified hop extract shall not exceed 125 parts per million of hexane; 150 parts per million of ethylene dichloride, methylene chloride, or trichloroethylene; or 250 parts per million of isopropyl alcohol or methyl alcohol.

(6) The additive is manufactured from hops by an initial extraction and fractionation using one or more of the solvents listed in paragraph (b)(5) of this section followed by: Hydrogenation using palladium as a catalyst in methyl alcohol, ethyl alcohol, or isopropyl alcohol acidified with hydrochloric or sulfuric acid; oxidation with peracetic acid; isomerization by calcium chloride or magnesium chloride treatment in ethylene dichloride, methylene chloride, or trichloroethylene (alternatively, the hydrogenation and isomerization steps may be performed in reverse order); and a further sequence of extractions and fractionations using one or more of the solvents listed in paragraph (b)(5) of this section. The additive shall meet the residue limitations as prescribed in paragraph (b)(5) of this section.

(7) The additive is manufactured from hops as set forth in paragraph (b)(6) of this section followed by reduction with sodium borohydride in aqueous alkaline methyl alcohol, and a sequence of extractions and fractionations using one or more of the solvents listed in paragraph (b)(5) of this section. The additive shall meet the residue limitations as prescribed in paragraph (b)(5) of this section, and a boron content level not in excess of 300 parts per million (0.0300 percent), calculated as boron.

(8) The additive is manufactured from hops as a nonisomerizable nonvolatile hop resin by an initial extraction and fractionation using one or more of the solvents listed in paragraph (b)(5) of this section followed by a sequence of aqueous extractions and removal of nonaqueous solvents to less than 0.5 percent. The additive is added to the wort before or during cooking in the manufacture of beer.

§ 172.575 Quinine.

Quinine, as the hydrochloride sale or sulfate salt, may be safely used in food in accordance with the following conditions:

Uses	*Limitations*
In carbonated beverages as a flavor.	Not to exceed 83 parts per million, as quinine. Label shall bear a prominent declaration of the presence of quinine either by the use of the word "quinine" in the name of the article or through a separate declaration.

§ 172.580 Safrole-free extract of sassafras.

The food additive safrole-free extract of sassafras may be safely used in accordance with the following prescribed conditions:

(a) The additive is the aqueous extract obtained from the root bark of the plant

Sassafras albidum (Nuttall) Nees (Fam. Lauraceae).

(b) It is obtained by extracting the bark with dilute alcohol, first concentrating the alcoholic solution by vacuum distillation, then diluting the concentrate with water and discarding the oily fraction.

(c) The purified aqueous extract is safrole-free.

(d) It is used as a flavoring in food.

§ 172.585 Sugar beet extract flavor base.

Sugar beet extract flavor base may be safely used in food in accordance with the provisions of this section.

(a) Sugar beet extract flavor base is the concentrated residue of soluble sugar beet extractives from which sugar and glutamic acid have been recovered, and which has been subjected to ion exchange to minimize the concentration of naturally occurring trace minerals.

(b) It is used as a flavor in food.

§ 172.590 Yeast-malt sprout extract.

Yeast-malt sprout extract, as described in this section, may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is produced by partial hydrolysis of yeast extract (derived from *Saccharomyces cerevisiae*, *Saccharomyces fragilis*, or *Candida utilis*) using the sprout portion of malt barley as the source of enzymes. The additive contains a maximum of 6 percent 5′ nucleotides by weight.

(b) The additive may be used as a flavor enhancer in food at a level not in excess of that reasonably required to produce the intended effect.

Subpart G—Gums, Chewing Gum Bases and Related Substances

§ 172.610 Arabinogalactan.

Arabinogalactan may be safely used in food in accordance with the following conditions:

(a) Arabinogalactan is a polysaccharide extracted by water from Western larch wood, having galactose units and arabinose units in the approximate ratio of six to one.

(b) It is used in the following foods in the minimum quantity required to produce its intended effect as an emulsifier, stabilizer, binder, or bodying agent: Essential oils, nonnutritive sweeteners, flavor bases, nonstandardized dressings, and pudding mixes.

§ 172.615 Chewing gum base.

The food additive chewing gum base may be safely used in the manufacture of chewing gum in accordance with the following prescribed conditions:

(a) The food additive consists of one or more of the following substances that meet the specifications and limitations prescribed in this paragraph, used in amounts not to exceed those required to produce the intended physical or other technical effect.

MASTICATORY SUBSTANCES

NATURAL (COAGULATED OR CONCENTRATED LATICES) OF VEGETABLE ORIGIN

Family	*Genus and species*
Sapotaceae:	
Chicle	Manilkara zapotilla Gilly and Manilkara chicle Gilly.
Chiquibul	Manilkara zapotilla Gilly.
Crown gum	Manilkara zapotilla Gilly and Manilkara chicle Gilly.
Gutta hang kang	Palaquium leiocarpum Boerl. and Palaquium oblongifolium Burck.
Massaranduba balata (and the solvent-free resin extract of Massaranduba balata).	Manilkara huberi (Ducke) Chevalier.
Massaranduba chocolate	Manilkara solimoesensis Gilly.
Nispero	Manilkara zapotilla Gilly and Manilkara chicle Gilly.
Rosidinha (rosadinha)	Micropholis (also known as Sideroxylon) spp.
Venezuelan chicle	Manilkara williamsii Standley and related spp.
Apocynaceae:	
Jelutong	Dyera costulata Hook, F. and Dyera lowii Hook, F.
Leche caspi (sorva)	Couma macrocarpa Barb. Rodr.
Pendare	Couma macrocarpa Barb. Rodr. and Couma utilis (Mart.) Muell. Arg.
Perillo	Couma macrocarpa Barb. Rodr. and Couma utilis (Mart.) Muell. Arg.
Moraceae:	
Leche de vaca	Brosimum utile (H.B.K.) Pittier and Poulsenia spp.; also Lacmellea standleyi (Woodson), Monachino (Apocynaceae).
Niger gutta	Ficus platyphylla Del.
Tunu (tuno)	Castilla fallax Cook.
Euphorbiaceae:	
Chilte	Cnidoscolus (also known as Jatropha) elasticus Lundell and Cnidoscolus tepiquensis (Cost. and Gall.) McVaugh.
Natural rubber (smoked sheet and latex solids).	Hevea brasiliensis.

Synthetic	*Specifications*
Butadiene-styrene rubber	Basic polymer.
Isobutylene - isoprene copolymer (butyl rubber).	Do.
Paraffin	Synthesized by Fischer-Tropsch process from carbon monoxide and hydrogen, which are catalytically converted to a mixture of paraffin hydrocarbons. Lower molecular weight fractions are removed by distillation. The residue is hydrogenated and further treated by percolation through activated charcoal. The product has a congealing point of 200° F–210° F as determined by A.S.T.M. D–938–49 method; a maximum oil content of 0.5 percent as determined by A.S.T.M. D–721–56T method; and an absorptivity of less than 0.01 at 290 millimicrons in decahydronaphthalene at 190° F as determined by A.S.T.M. 131 method.
Petroleum wax	Complying with § 172.886.
Petroleum wax synthetic	Complying with § 172.888.
Polyethylene	Molecular weight 2,000–21,000.
Polyisobutylene	Minimum molecular weight 37,000 (Flory).
Polyvinyl acetate	Molecular weight, minimum 2,000.

PLASTICIZING MATERIALS (SOFTENERS)

Glycerol ester of partially dimerized rosin.	Having an acid number of 3–8, a drop-softening point of 109° C–119° C, and a color of M or paler.
Glycerol ester of partially hydrogenated gum or wood rosin.	Having an acid number of 3–10, a drop-softening point of 79° C–88° C, and a color of N or paler.
Glycerol ester of polymerized rosin	Having an acid number of 3–12, a melting-point range 80° C–126° C, and a color of M or paler.
Glycerol ester of gum rosin	Having an acid number of 5–9, a drop-softening point of 88° C–96° C, and a color of N or paler. The ester is purified by steam stripping.
Glycerol ester of tall oil rosin	Having an acid number of 5–12, a softening point (ring and ball) of 80°–88° C, and a color of N or paler. The ester is purified by steam stripping.
Glycerol ester of wood rosin	Having an acid number of 3–8, a drop-softening point of 88° C–96° C, and a color of N or paler. The ester is purified by steam stripping.
Lanolin	
Methyl ester of rosin, partially hydrogenated.	Having an acid number of 4–8, a refractive index of 1.5170–1.5205 at 20° C, and a viscosity of 23–66 poises at 25° C. The ester is purified by steam stripping.

PLASTICIZING MATERIALS (SOFTENERS)—Continued	
Pentaerythritol ester of partially hydrogenated gum or wood resin.	Having an acid number of 7–16, a drop-softening point of 102° C–110° C, and a color of K or paler.
Pentaerythritol ester of gum or wood rosin.	Having an acid number of 6–16, a drop-softening point of 109° C–116° C, and a color of M or paler.
Rice bran wax	Complying with § 172.890.
Stearic acid	Complying with § 172.860.
Sodium and potassium stearates	Complying with § 172.863.
TERPENE RESINS	
Synthetic resin	Consisting of polymers of α-pinene, β-pinene, and/or dipentene; acid value less than 5, saponification number less than 5, and color less than 4 on the Gardner scale as measured in 50 percent mineral spirit solution.
Natural resin	Consisting of polymers of α-pinene; softening point minimum 155° C, determined by U.S.P. closed-capillary method.
ANTIOXIDANTS	
Butylated hydroxyanisole	
Butylated hydroxytoluene	Not to exceed antioxidant content of 0.1% when used alone or in any combination.
Propyl gallate	
MISCELLANEOUS	
Sodium sulfate	
Sodium sulfide	Reaction-control agent in synthetic polymer production.

(b) In addition to the substances listed in paragraph (a) of this section, chewing gum base may also include substances generally recognized as safe in food.

(c) To assure safe use of the additive, in addition to the other information required by the act, the label and labeling of the food additive shall bear the name of the additive, "chewing gum base." As used in this paragraph, the term "chewing gum base" means the manufactured or partially manufactured nonnutritive masticatory substance comprised of one or more of the ingredients named and so defined in paragraph (a) of this section.

§ 172.620 Carrageenan.

The food additive carrageenan may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the refined hydrocolloid prepared by aqueous extraction from the following members of the families Gigartinaceae and Solieriaceae of the class Rodophyceae (red seaweed):

Chondrus crispus.
Chondrus ocellatus.
Eucheuma cottonii.
Eucheuma spinosum.
Gigartina acicularis.
Gigartina pistillata.
Gigartina radula.
Gigartina stellata.

(b) The food additive conforms to the following conditions:

(1) It is a sulfated polysaccharide the dominant hexose units of which are galactose and anhydrogalactose.

(2) Range of sulfate content: 20 percent to 40 percent on a dry-weight basis.

(c) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the additive, carrageenan.

§ 172.623 Carrageenan with polysorbate 80.

Carrageenan otherwise meeting the definition and specifications of § 172.620 (a) and (b) and salts of carrageenan otherwise meeting the definition of § 172.626(a) may be safely produced with the use of polysorbate 80 meeting the specifications and requirements of § 172.840 (a) and (b) in accordance with the following prescribed conditions:

(a) The polysorbate 80 is used only to facilitate separation of sheeted carrageenan and salts of carrageenan from drying rolls.

(b) The carrageenan and salts of carrageenan contain not more than 5 percent by weight of polysorbate 80, and the final food containing the additives contains polysorbate 80 in an amount not to exceed 500 parts per million.

(c) The carrageenan and salts of carrageenan so produced are used only in producing foods in gel form and only for the purposes defined in § 172.620(c) and § 172.626(b), respectively.

(d) The carrageenan and salts of carrageenan so produced are not used in foods for which standards of identity exist unless the standards provide for the use of carrageenan, or salts or carrageenan, combined with polysorbate 80.

(e) The carrageenan and salts of carrageenan produced in accordance with this section, and foods containing the same, in addition to the other requirements of the act, are labeled to show the presence of polysorbate 80, and the label or labeling of the carrageenan and salts of carrageenan so produced bear adequate directions for use.

§ 172.626 Salts of carrageenan.

The food additive salts of carrageenan may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive consists of carrageenan, meeting the provisions of § 172.620, modified by increasing the concentration of one of the naturally occurring salts (ammonium, calcium, potassium, or sodium) of carrageenan to the level that it is the dominant salt in the additive.

(b) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the salt of carrageenan that dominates the mixture by reason of the modification, e.g., "sodium carrageenan", "potassium carrageenan", etc.

§ 172.655 Furcelleran.

The food additive furcelleran may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the refined hydrocolloid prepared by aqueous extraction of furcellaria fastigiata of the class Rodophyceae (red seaweed).

(b) The food additive conforms to the following:

(1) It is a sulfated polysaccharide the dominant hexose units of which are galactose and anhydrogalactose.

(2) Range of sulfate content: 8 percent to 19 percent, on a dry-weight basis.

(c) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the additive, furcelleran.

§ 172.660 Salts of furcelleran.

The food additive salts of furcelleran may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive consists of furcelleran, meeting the provisions of § 172.655, modified by increasing the concentration of one of the naturally occurring salts (ammonium, calcium, potassium, or sodium) of furcelleran to the level that it is the dominant salt in the additive.

(b) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the salt of furcelleran that dominates the mixture by reason of the modification, e.g., "sodium furcelleran", "potassium furcelleran", etc.

§ 172.695 Xanthan gum.

The food additive xanthan gum may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a polysaccharide gum derived from *Xanthomonas campestris* by a pure-culture fermentation

process and purified by recovery with isopropyl alcohol. It contains D-glucose, D-mannose, and D-glucuronic acid as the dominant hexose units and is manufactured as the sodium, potassium, or calcium salt.

(b) The strain of *Xanthomonas campestris* is nonpathogenic and nontoxic in man or other animals.

(c) The additive is produced by a process that renders it free of viable cells of *Xanthomonas campestris*.

(d) The additive meets the following specifications:

(1) Residual isopropyl alcohol not to exceed 750 parts per million.

(2) An aqueous solution containing 1 percent of the additive and 1 percent of potassium chloride stirred for 2 hours has a minimum viscosity of 600 centipoises at 75° F, as determined by Brookfield Viscometer, Model LVF (or equivalent), using a No. 3 spindle at 60 r.p.m., and the ratio of viscosities at 75 ° F and 150 ° F is in the range of 1.02 to 1.45.

(3) Positive for xanthan gum when subjected to the following procedure:

LOCUST BEAN GUM GEL TEST

Blend on a weighing paper or in a weighing pan 1.0 gram of powdered locust bean gum with 1.0 gram of the powdered polysaccharide to be tested. Add the blend slowly (approximately ½ minute) at the point of maximum agitation to a stirred solution of 200 milliliters of distilled water previously heated to 80° C in a 400-milliliter beaker. Continue mechanical stirring until the mixture is in solution, but stir for a minimum time of 30 minutes. Do not allow the water temperature to drop below 60° C.

Set the beaker and its contents aside to cool in the absence of agitation. Allow a minimum time of 2 hours for cooling. Examine the cooled beaker contents for a firm rubbery gel formation after the temperature drops below 40° C.

In the event that a gel is obtained, make up a 1 percent solution of the polysaccharide to be tested in 200 milliliters of distilled water previously heated to 80° C (omit the locust bean gum). Allow the solution to cool without agitation as before. Formation of a gel on cooling indicates that the sample is a gelling polysaccharide and not xanthan gum.

Record the sample as "positive" for xanthan gum if a firm, rubbery gel forms in the presence of locust bean gum but not in its absence. Record the sample as "negative" for xanthan gum if no gel forms or if a soft or brittle gel forms both with locust bean gum and in a 1 percent solution of the sample (containing no locust bean gum).

(4) Positive for xanthan gum when subjected to the following procedure:

PYRUVIC ACID TEST

Pipet 10 milliliters of an 0.6 percent solution of the polysaccharide in distilled water (60 milligrams of water-soluble gum) into a 50-milliliter flask equipped with a standard taper glass joint. Pipet in 20 milliliters of 1*N* hydrochloric acid. Weigh the flask. Reflux the mixture for 3 hours. Take precautions to avoid loss of vapor during the refluxing. Cool the solution to room temperature. Add distilled water to make up any weight loss from the flask contents.

Pipet 1 milliliter of a 2,4-dinitrophenylhydrazine reagent (0.5 percent in 2*N* hydrochloric acid) into a 30-milliliter separatory funnel followed by a 2-milliliter aliquot (4 milligrams of water-soluble gum) of the polysaccharide hydrolyzate. Mix and allow the reaction mixture to stand at room temperature for 5 minutes. Extract the mixture with 5 milliliters of ethyl acetate. Discard the aqueous layer.

Extract the hydrazone from the ethyl acetate with three 5 milliliter portions of 10 percent sodium carbonate solution. Dilute the combined sodium carbonate extracts to 100 milliliters with additional 10 percent sodium carbonate in a 10-milliliter volumetric flask. Measure the optical density of the sodium carbonate solution at 375 millimicrons.

Compare the results with a curve of the optical density versus concentration of an authentic sample of pyruvic acid that has been run through the procedure starting with the preparation of the hydrazone.

Record the percent by weight of pyruvic acid in the test polysaccharide. Note "positive" for xanthan gum if the sample contains more than 1.5 percent of pyruvic acid and "negative" for xanthan gum if the sample contains less than 1.5 percent of pyruvic acid by weight.

(e) The additive is used or intended for use in accordance with good manufacturing practice as a stabilizer, emulsifier, thickener, suspending agent, bodying agent, or foam enhancer in foods for which standards of identity established under section 401 of the act do not preclude such use.

(f) To assure safe use of the additive:

(1) The label of its container shall bear, in addition to other information required by the act, the name of the additive and the designation "food grade".

(2) The label or labeling of the food additive container shall bear adequate directions for use.

Subpart H—Other Specific Usage Additives

§ 172.710 Adjuvants for pesticide use dilutions.

The following surfactants and related adjuvants may be safely added to pesticide use dilutions by a grower or applicant prior to application to the growing crop:

n-Alkyl (C_8-C_{18}) amine acetate, where the alkyl groups (C_8-C_{18}) are derived from coconut oil, as a surfactant in emulsifier blends at levels not in excess of 5 percent by weight of the emulsifier blends that are added to herbicides for application to corn and sorghum.

Di-*n*-alkyl (C_8-C_{18}) dimethyl ammonium chloride, where the alkyl groups (C_8-C_{18}) are derived from coconut oil, as surfactants in emulsifier blends at levels not in excess of 5 percent by weight of emulsifier blends that are added to herbicides for application to corn or sorghum.

Diethanolamide condensate based on a mixture of saturated and unsaturated soybean oil fatty acids (C_{16}-C_{18}) as a surfactant in emulsifier blends that are added to the herbicide atrazine for application to corn.

Diethanolamide condensate based on stripped coconut fatty acids (C_{12}-C_{18}) as a surfactant in emulsifier blends that are added to the herbicide atrazine for application to corn.

α-(*p*-Dodecylphenyl) - *omega* - hydroxypoly (oxyethylene) produced by the condensation of 1 mole of dodecylphenol (dodecyl group is a propylene tetramer isomer) with an average of 4–14 or 30–70 moles of ethylene oxide; if a blend of products issued, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 4–14 or 30–70.

Ethylene dichloride.

Polyglyceryl phthalate ester of coconut oil fatty acids.

α-[*p*-(1,1,3,3-Tetramethylbutyl) phenyl]-*omega*-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p*-(1,1,3,3-tetramethylbutyl) phenol with an average of 4–14 or 30–70 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 4–14 or 30–70.

α-[*p*-(1,1,3,3-Tetramethylbutyl) phenyl]-*omega*-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p*-(1,1,3,3-tetramethylbutyl) phenol with 1 mole of ethylene oxide.

Sodium acrylate and acrylamide copolymer with a minimum average molecular weight of 10,000,000 in which 30 percent of the polymer is comprised of acrylate units and 70 percent acrylamide units, for use as a drift control agent in herbicide formulations applied to crops at a level not to exceed 0.5 ounces of the additive per acre.

§ 172.712 Dimethyl dialkyl ammonium chloride.

Dimethyl dialkyl ammonium chloride may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is produced by ammonolysis of natural tallow fatty acids to form amines that are subsequently reacted with methyl chloride to form the quaternary ammonium compounds consisting primarily of dimethyl dioctadecyl ammonium chloride and dimethyl dihexadecyl ammonium chloride. The additive may contain residues of isopropyl alcohol not in excess of 18 percent by weight when used as a processing solvent.

(b) The food additive contains not more than a total of 2 percent by weight of free amine and amine hydrochloride.

(c) The food additive is used as a decolorizing agent in the clarification of refinery sugar liquors. It is added only at the defecation/clarification stage of sugar liquor refining in an amount not to exceed 700 parts per million by weight of sugar solids.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear, in addition to other information required by the act, adequate directions to assure use in compliance with paragraph (c) of this section.

§ 172.715 Calcium lignosulfonate.

Calcium lignosulfonate may be safely used in or on food, subject to the provisions of this section.

(a) Calcium lignosulfonate consists of sulfonated lignin, primarily as calcium and sodium salts.

(b) It is used in an amount not to exceed that reasonably required to accomplish the intended physical or technical effect when added as a dispersing agent and stabilizer in pesticides for preharvest or postharvest application to bananas.

§ 172.720 Calcium lactobionate.

The food additive calcium lactobionate may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the calcium salt of lactobionic acid (4-(*β*, D-galactosido)-D-gluconic acid) produced by the oxidation of lactose.

(b) It is used or intended for use as a firming agent in dry pudding mixes at a level not greater than that required to accomplish the intended effect.

§ 172.725 Gibberellic acid and its potassium salt.

The food additives gibberellic acid and its potassium salt may be used in the malting of barley in accordance with the following prescribed conditions:

(a) The additives meet the following specifications:

(1) The gibberellic acid is produced by deep-culture fermentation of a suitable nutrient medium by a strain of Fusarium moniliforme or a selection of this culture.

(2) The gibberellic acid produced is of 80 percent purity or better.

(3) The empirical formula of gibberellic acid is represented by $C_{19}H_{22}O_6$.

(4) Potassium gibberellate is the potassium salt of the specified gibberellic acid.

(5) The potassium gibberellate is of 80 percent purity or better.

(6) The gibberellic acid or potassium gibberellate may be diluted with substances generally recognized as safe in foods or with salts of fatty acids conforming to § 172.863.

(b) They are used or intended for use in the malting of barley under conditions whereby the amount of either or both additives present in the malt is not in excess of 2 parts per million expressed as gibberellic acid, and the treated malt is to be used in the production of fermented malt beverages or distilled spirits only, whereby the finished distilled spirits contain none and the finished malt beverage contains not more than 0.5 part per million of gibberellic acid.

(c) To insure the safe use of the food additives the label of the package shall bear, in addition to the other information required by the act:

(1) The name of the additive, "gibberellic acid" or "potassium gibberellate", whichever is appropriate.

(2) An accurate statement of the concentration of the additive contained in the package.

(3) Adequate use directions to provide not more than 2 parts per million of gibberellic acid in the finished malt.

(4) Adequate labeling directions to provide that the final malt is properly labeled as described in paragraph (d) of this section.

(d) To insure the safe use of the additive the label of the treated malt shall bear, in addition to the other information required by the act, the statements:

(1) "Contains not more than 2 parts per million _____", the blank being filled in with the words "gibberellic acid" or "potassium gibberellate", whichever is appropriate; and

(2) "Brewer's malt—To be used in the production of fermented malt beverages only" or "Distiller's malt—To be used in the production of distilled spirits only", whichever is appropriate.

§ 172.730 Potassium bromate.

The food additive potassium bromate may be safely used in the malting of barley under the following prescribed conditions:

(a) (1) It is used or intended for use in the malting of barley under conditions whereby the amount of the additive present in the malt from the treatment does not exceed 75 parts per million of bromate (calculated as Br), and the treated malt is used only in the production of fermented malt beverages or distilled spirits.

(2) The total residue of inorganic bromides in fermented malt beverages, resulting from the use of the treated malt plus additional residues of inorganic bromides that may be present from uses in accordance with other regulations in this chapter promulgated under sections 408 and/or 409 of the act, does not exceed 25 parts per million of bromide (calculated as Br). No tolerance is established for bromide in distilled spirits because there is evidence that inorganic bromides do not pass over in the distillation process.

(b) To assure safe use of the additive, the label or labeling of the food additive shall bear, in addition to the other information required by the act, the following:

(1) The name of the additive.

(2) Adequate directions for use.

(c) To assure safe use of the additive, the label or labeling of the treated malt shall bear, in addition to other information required by the act, the statement, "Brewer's Malt—To be used in the production of fermented malt beverages only", or "Distiller's Malt—To be used in the production of distilled spirits only", whichever is the case.

§ 172.735 Glycerol ester of wood rosin.

Glycerol ester of wood rosin may be safely used in food in accordance with the following prescribed conditions:

(a) It has an acid number of 3 to 9, a drop-softening point of 88° C–96° C; and a color of N or paler as determined in accordance with Official Naval Stores Standards of the United States. It is purified by countercurrent steam distillation.

(b) It is used to adjust the density of citrus oils used in the preparation of beverages whereby the amount of the additive does not exceed 100 parts per million of the finished beverage.

§ 172.755 Stearyl monoglyceridyl citrate.

The food additive stearyl monoglyceridyl citrate may be safely used in food in accordance with the following provisions:

(a) The additive is prepared by controlled chemical reaction of the following:

Reactant	*Limitations*
Citric acid	
Monoglycerides of fatty acids.	Prepared by the glycerolysis of edible fats and oils or derived from fatty acids conforming with § 172.860.
Stearyl alcohol	Derived from fatty acids conforming with § 172.860, or derived synthetically in conformity with § 172.864.

(b) The additive stearyl monoglyceridyl citrate, produced as described under paragraph (a) of this section, meets the following specifications:

Acid number	40 to 52.
Total citric acid	15 to 18 percent.
Saponification number	215–255.

(c) The additive is used or intended for use as an emulsion stabilizer in or with shortenings containing emulsifiers.

§ 172.765 Succistearin (stearoyl propylene glycol hydrogen succinate).

The food additive succistearin (stearoyl propylene glycol hydrogen succinate) may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is the reaction product of succinic anhydride, fully hydrogenated vegetable oil (predominantly C_{16} or C_{18} fatty acid chain length), and propylene glycol.

(b) The additive meets the following specifications:

Acid number 50–150.
Hydroxyl number 15–50.
Succinated ester content 45–75 percent.

(c) The additive is used or intended for use as an emulsifier in or with shortenings and edible oils intended for use in cakes, cake mixes, fillings, icings, pastries, and toppings, in accordance with good manufacturing practice.

§ 172.770 Ethylene oxide polymer.

The polymer of ethylene oxide may be safely used as a foam stabilizer in fermented malt beverages in accordance with the following conditions.

(a) It is the polymer of ethylene oxide having a minimum viscosity of 1,500 centipoises in a 1 percent aqueous solution at 25° C.

(b) It is used at a level not to exceed 300 parts per million by weight of the fermented malt beverage.

(c) The label of the additive bears directions for use to insure compliance with paragraph (b) of this section.

§ 172.775 Methacrylic acid-divinylbenzene copolymer.

Methacrylic acid-divinylbenzene copolymer may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is produced by the polymerization of methacrylic acid and divinylbenzene. The divinylbenzene functions as a cross-linking agent and constitutes a minimum of 4 percent of the polymer.

(b) Aqueous extractives from the additive do not exceed 2 percent (dry basis) after 24 hours at 25° C.

(c) The additive is used as a carrier of vitamin B_{12} in foods for special dietary use.

Subpart I—Multipurpose Additives

§ 172.802 Acetone peroxides.

The food additive acetone peroxides may be safely used in flour, and in bread and rolls where standards of identity do not preclude its use, in accordance with the following prescribed conditions:

(a) The additive is a mixture of monomeric and linear dimeric acetone peroxide, with minor proportions of higher polymers, manufactured by reaction of hydrogen peroxide and acetone.

(b) The additive may be mixed with an edible carrier to give a concentration of: (1) 3 grams to 10 grams of hydrogen peroxide equivalent per 100 grams of the additive, plus carrier, for use in flour maturing and bleaching; or (2) approximately 0.75 gram of hydrogen peroxide equivalent per 100 grams of the additive, plus carrier, for use in dough conditioning.

(c) It is used or intended for use: (1) In maturing and bleaching of flour in a quantity not more than sufficient for such effect; and (2) as a dough-conditioning agent in bread and roll production at not to exceed the quantity of hydrogen peroxide equivalent necessary for the artificial maturing effect.

(d) To insure safe use of the additive, the label of the food additive container and any intermediate premix thereof shall bear, in addition to the other information required by the act:

(1) The name of the additive, "acetone peroxides".

(2) The concentration of the additive expressed in hydrogen peroxide equivalents per 100 grams.

(3) Adequate use directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

§ 172.804 Aspartame.

The food additive aspartame may be safely used in food in accordance with good manufacturing practice as a sweetening agent or for an authorized technological purpose in foods for which standards of identity established under section 401 of the act do not preclude such use under the following conditions:

(a) Aspartame is the chemical

1-methyl *N*-L-α-aspartyl-L-phenylalanine ($C_{14}H_{18}N_2O_5$).

(b) The additive meets the following specifications:

(1) Not less than 98.0 percent and not more than the equivalent of 102.0 percent $C_{14}H_{18}N_2O_5$ (aspartame), calculated on the dried basis (4 hours at 105° C), as determined by the following analytical method.

APPARATUS

Titration vessel. Glass beaker or flask, 150 milliliters.

Buret. 50 milliliters with 0.1-milliliter gradations, equipped with tetrafluoroethylene polymer stopcock.

Aluminum foil.

Optional equipment. Magnetic stirrer and tetrafluoroethylene polymer-coated magnetic bar.

REAGENTS

Lithium metal.

Methyl alcohol. Absolute, A.C.S. reagent grade.

Benzene. Anhydrous, A.C.S. reagent grade.

Thymol blue (thymolsulfonephthalein). A.C.S. reagent grade.

Ethyl alcohol. 95 percent.

Benzoic acid. A.C.S. reagent grade, of specified purity dried at 80° C.

N,N-Dimethylformamide. A.C.S. reagent grade.

Lithium methoxide solution. 0.1 normal; dissolve 600 milligrams of lithium metal in 150 milliliters of absolute methyl alcohol and 850 milliliters of benzene. Filter the solution if cloudy.

Thymol blue solution. Dissolve 100 milligrams of thymol blue in 100 milliliters of 95 percent ethyl alcohol. Filter if necessary.

PROCEDURE

General instructions. Perform in triplicate both the standardization of the lithium methoxide solution and the titration of the sample. Perform one titration of the solvent blank, i.e., *N,N*-dimethylformamide. Cover the titration vessel with aluminum foil while dissolving the samples and throughout the titration to decrease carbon dioxide absorption.

Titration of solvent blank. Add 35 milliliters of *N,N*-dimethylformamide to the titration vessel. Add 5 drops of the thymol blue solution and titrate the mixture with lithium methoxide solution to an end point indicated by a color change from yellow to blue.

Determination of normality of the lithium methoxide solution. Place a weighed sample of benzoic acid (approximately 80 milligrams) in the titration vessel, add 35 milliliters of *N,N*-dimethylformamide and dissolve the sample. Add 5 drops of thymol blue solution to the dissolved sample and titrate with the lithium methoxide solution to an end point indicated by a color change from yellow to blue.

Titration of the aspartame sample. Place a weighed sample of aspartame (approximately 150 milligrams dried at 105° C for 4 hours and stored in a desiccator) in the titration vessel, add 35 milliliters of *N,N*-dimethylformamide and dissolve the sample. Add 5 drops of thymol blue solution to the dissolved sample and titrate with the lithium methoxide solution to an end point indicated by a color change from yellow to blue

CALCULATIONS

$$N=\frac{J}{(122.12)\ (S-B)}$$

Percent aspartame in sample=

$$\frac{(294.3)\ (A-B)\ (N)}{K}\times 100$$

Where:
N=Accurate normality of the lithium methoxide solution.
S=Milliliters of lithium methoxide solution required to titrate the benzoic acid.
A=Milliliters of lithium methoxide solution required to titrate the aspartame sample.
B=Milliliters of lithium methoxide solution required to titrate the solvent blank.
J =Milligrams of benzoic acid standard.
K=Milligrams of aspartame sample.

(2) Specific rotation $[\alpha]_D^{20}$, shall be between +12.5° and +17.5°, calculated on the dried basis (4 hours at 105° C) in accordance with the test for optical rotation described in the "Food Chemicals Codex," 2nd Ed. (1972),[1] page 939. Weigh accurately about 4 grams of sample and dissolve it in sufficient 15*N* formic acid to make exactly 100 milliliters of solution, and complete the determination of the rotation in a 100-millimeter tube within 30 minutes after preparing the solution.

(3) 5-Benzyl-3,6-dioxo-2-piperazineacetic acid (diketopiperazine) not to exceed 2.0 percent as determined by the following analytical method:

APPARATUS

Gas chromatograph. With hydrogen flame ionization detector and designed for handling glass columns with on-column injection (Micro-Tek 220 or equivalent). Chromatograph conditions should be optimized to obtain maximum resolution for the specific instrument used. To preclude buildup of silicon oxide, (clean the detector with acetone frequently. Approximate operating conditions are:

Column temperature: 200° C.
Detector temperature: 275° C.
Inlet temperature: 200° C.
Carrier gas (helium) flow rate: 75 milliliters per minute.
Hydrogen and air flow to burner: Optimize to give maximum sensitivity.
Sample size: 3 microliters.
Elution time: 7–9 minutes.
Recorder: 1 millivolt full scale (for the Micro-Tek 220, the attenuation is 16x10).
Chromatograph column: 6 feet x 4 millimeters I.D. glass column packed with OV–1 on 80–100 mesh Supelcoport (Supelco, Inc., or equivalent). Condition the column overnight at 250° C before readjustment and equilibration to the operation conditions.

Oven. Capable of maintaining 80±1° C for 30 minutes.

Glass manifold. Suitable for evaporating samples to dryness over steam bath; the apparatus may have an optional gas flow over the sample to enhance the rate of solvent evaporation.

Vials. 2-dram size with tetrafluoroethylene polymer-lined cap.

REAGENTS

N,N-Dimethylformamide. A.C.S. reagent grade.

N, O-Bis(trimethylsilyl) acetamide.

Silylation reagent. Dilute by volume three parts *N,O*-bis (trimethylsilyl) acetamide with two parts *N,N*-dimethylformamide. Prepare fresh before use.

Methyl alcohol. Anyhdrous, A.C.S. reagent grade.

5-Benzyl-3,6-dioxo-2-piperazineacetic acid. Specifications: Purity, not less than 99 percent; minimum melting point, 243° C; specific rotation of a 1 percent solution (in acetic acid), between −9° and −11°; total impurities determined by thin layer chromatography, less than 0.5 percent; impurities determined by gas chromatography, less than 1 percent for any single impurity. A sample of the reagent and test procedures for verification of specifications may be obtained from Food Chemicals Codex, National Academy of Sciences, 2101 Constitution Ave., NW., Washington, DC 20037.

PROCEDURE

Preparation of the standard. Place a weighed sample of 5-benzyl-3,6-dioxo-2-piperazineacetic acid (25 milligrams) into a 50-milliliter volumetric flask. Add methyl alcohol to dissolve the solid standard and dilute to volume. Dilute a 10-milliliter portion of the above solution to 50 milliliters with methyl alcohol in another 50-milliliter volumetric flask. The concentration of this standard solution is 0.1 milligram per milliliter. Pipet 2 milliliters of the standard solution into a 2-dram vial and evaporate the solvent to dryness. Add 1 milliliter of the silylation reagent to the dried sample, cap the vial tightly, shake and place in an 80° C oven for 30 minutes. Remove from oven, shake vial 15 seconds and cool to room temperature. Inject 3 microliters of this solution into the gas chromatograph and measure the peak height. The standard should be

[1] Copies may be obtained from: The National Academy of Sciences, 2101 Constitution Ave. NW., Washington, D.C. 20037.

injected either immediately before or after each sample for proper quantification.

Preparation of the aspartame sample. Place a weighed sample of aspartame (approximately 10 milligrams) into a 2-dram vial. Add 1 milliliter of silylation reagent to the vial, cap tightly, shake and place in an 80° C oven for 30 minutes. Remove from oven, shake vial 15 seconds and cool to room temperature. Inject 3 microliters of this solution into the gas chromatograph and measure the subject compound peak height.

CALCULATION

$$\text{Milligrams of 5-benzyl-3,6-dioxo-2-piperazineacetic acid in aspartame} = \frac{\text{peak height of aspartame sample}}{\text{peak height of standard sample}} \times 0.2$$

$$\text{Percent 5-benzyl-3,6-dioxo-2-piperazineacetic acid in aspartame} = \frac{\text{milligrams of subject compound in aspartame}}{\text{milligrams of aspartame sample}} \times 100.$$

(c) The additive may be used as a sweetener in the following foods:

(1) Dry, free-flowing sugar substitutes for table use (not to include use in cooking) in package units not to exceed the sweetening equivalent of 2 teaspoonfuls of sugar.

(2) Sugar substitute tablets for sweetening hot beverages, including coffee and tea. L-leucine may be used as a lubricant in the manufacture of such tablets at a level not to exceed 3.5 percent of the weight of the tablet.

(3) Cold breakfasts cereals.

(4) Chewing gum.

(5) Dry bases for:

(i) Beverages.

(ii) Instant coffee and tea.

(iii) Gelatins, puddings, and fillings.

(iv) Dairy product analog toppings.

(d) The additive may be used as a flavor enhancer in chewing gum.

(e) To assure safe use of the additive, in addition to the other information required by the act:

(1) The principal display panel of any intermediate mix of the additive for manufacturing purposes shall bear a statement of the concentration of the additive contained therein;

(2) The label of any food containing the additive shall bear, either on the principal display panel or on the information panel, the following statement: PHENYLKETONURICS: CONTAINS PHENYLALANINE

The statement shall appear in the labeling prominently and conspicuously as compared to other words, statements, designs or devices and in bold type and on clear contrasting background in order to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(3) When the additive is used in a sugar substitute for table use, its label shall bear instructions not to use in cooking or baking.

(f) If the food containing the additive purports to be or is represented for special dietary uses, it shall be labeled in compliance with Part 105 of this chapter.

NOTE: Section 172.804 (formerly § 121.1258) was stayed in its entirety at 40 FR 56907, Dec. 5, 1975.

§ 172.806 Azodicarbonamide.

The food additive azodicarbonamide may be safely used in food in accordance with the following prescribed conditions:

(a) It is used or intended for use:

(1) As an aging and bleaching ingredient in cereal flour in an amount not to exceed 2.05 grams per 100 pounds of flour (0.0045 percent; 45 parts per million).

(2) As a dough conditioner in bread baking in a total amount not to exceed 0.0045 percent (45 parts per million) by weight of the flour used, including any quantity of azodicarbonamide added to flour in accordance with paragraph (a)(1) of this section.

(b) To assure safe use of the additive:

(1) The label and labeling of the additive and any intermediate premix prepared therefrom shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive.

(ii) A statement of the concentration or the strength of the additive in any intermediate premixes.

(2) The label or labeling of the food additive shall also bear adequate directions for use.

§ 172.808 Copolymer condensates of ethylene oxide and propylene oxide.

Copolymer condensates of ethylene oxide and propylene oxide may be safely used in food under the following prescribed conditions:

(a) The additive consists of one of the following:

(1) α-Hydro - *omega* - hydroxy - poly (oxyethylene) poly(oxypropylene) - (55–61 moles) poly(oxyethylene) block copolymer, having a molecular weight range of 9,760–13,200 and a cloud point above 100° C in 1 percent aqueous solution.

(2) α-Hydro - *omega* - hydroxy - poly (oxyethylene) poly(oxypropylene) - (53–59 moles) poly(oxyethylene) (14 – 16 moles) block copolymer, having a molecular weight range of 3,500–4,125 and a cloud point of 9° C–12° C in 10 percent aqueous solution.

(3) α-Hydro-*omega*-hydroxy-poly(oxyethylene) / poly(oxypropylene) (minimum 15 moles)/poly(oxyethylene) block copolymer, having a minimum average molecular weight of 1900 and a minimum cloud point of 9° C–12° C in 10 percent aqueous solution.

(4) α-Hdyro-*omega*-hydroxy-poly(oxyethylene) poly(oxypropylene)-(51–57 moles) poly(oxyethylene) block copolymer, having an average molecular weight of 14,000 and a cloud point above 100° C in 1 percent aqueous solution.

(b) The additive is used or intended for use as follows:

(1) The additive identified in paragraph (a)(1) of this section is used in accordance with good manufacturing practice as a solubilizing and stabilizing agent in flavor concentrates (containing authorized flavoring oils) for use in foods for which standards of identity established under section 401 of the act do not preclude such use, provided that the weight of the additive does not exceed the weight of the flavoring oils in the flavor concentrate.

(2) The additive identified in paragraph (a)(2) of this section is used as a processing aid and wetting agent in combination with dioctyl sodium sulfosuccinate for fumaric acid as prescribed in § 172.810.

(3) The additive identified in paragraph (a)(3) of this section is used as a surfactant and defoaming agent, at levels not to exceed 0.05 percent by weight, in scald baths for poultry defeathering, followed by potable water rinse. The temperatures of the scald baths shall be not less than 125° F.

(4) The additive identified in paragraph (a)(4) of this section is used as a dough conditioner in yeast-leavened bakery products for which standards of identity established under section 401 of the act do not preclude such use, provided that the amount of the additive dose not exceed 0.5 percent by weight of the flour used.

§ 172.810 Dioctyl sodium sulfosuccinate.

The food additive dioctyl sodium sulfosuccinate which meets the specifications of the Food Chemicals Codex may be safely used in food in accordance with the following prescribed conditions:

(a) As a wetting agent in the following fumaric acid-acidulated foods: Dry gelatin dessert, dry beverage base, and fruit juice drinks, when standards of identity do not preclude such use. The labeling of the dry gelatin dessert and dry beverage base shall bear adequate directions for use, and the additive shall be used in such an amount that the finished gelatin dessert will contain not in excess of 15 parts per million of the additive and the finished beverage or fruit juice drink will contain not in excess of 10 parts per million of the additive.

(b) As a processing aid in sugar factories in the production of unrefined cane sugar, in an amount not in excess of 0.5 part per million of the additive per percentage point of sucrose in the juice, syrup, or massecuite being processed, and so used that the final molasses will contain no more than 25 parts per million of the additive.

(c) As a solubilizing agent on gums and hydrophilic colloids to be used in food as stabilizing and thickening agents, when standards of identity do not preclude such use. The additive is used in an amount not to exceed 0.5 percent by weight of the gums or hydrophilic colloids.

(d) As an emulsifying agent for cocoa fat in noncarbonated beverages containing cocoa, whereby the amount of the additive does not exceed 25 parts per million of the finished beverage.

(e) As a dispersing agent in "cocoa with dioctyl sodium sulfosuccinate for

manufacturing" that conforms to the provisions of § 163.117 of this chapter and the use limitations prescribed in § 172.520, in an amount not to exceed 0.4 percent by weight thereof.

(f) As a processing aid and wetting agent in combination with α-hydro-*omega*-hydroxy-poly(oxyethylene)poly(oxypropylene)(53–59 moles)poly(oxyethylene)(14–16 moles) block copolymer, having a molecular weight range of 3,500–4,125 and a cloud point of 9° C–12° C in 10 percent aqueous solution, for fumaric acid used in fumaric acid-acidulated dry beverage base and in fumaric acid-acidulated fruit juice drinks, when standards of identity do not preclude such use. The labeling of the dry beverage base shall bear adequate directions for use, and the additives shall be used in such an amount that the finished beverage or fruit juice drink will contain not in excess of a total of 10 parts per million of the dioctyl sodium sulfosuccinate-block copolymer combination.

§ 172.812 Glycine.

The food additive glycine may be safely used for technological purposes in food in accordance with the following prescribed conditions:

(a) The additive complies with the specifications prescribed in "*Food Chemicals Codex*," National Academy of Sciences/National Research Council (NAS/NRC) 2d edition (1972).[11]

(b) The additive is used or intended for use as follows:

Uses	*Limitations*
As a masking agent for the bitter aftertaste of saccharin used in manufactured beverages and beverage bases.	Not to exceed 0.2 percent in the finished beverage.
As a stabilizer in mono- and diglycerides prepared by the glycerolysis of edible fats or oils.	Not to exceed 0.02 percent of the mono- and diglycerides.

(c) To assure safe use of the additive, in addition to the other information required by the act:

(1) The labeling of the additive shall bear adequate directions for use of the additive in compliance with the provisions of this section.

(2) The labeling of beverage bases containing the additive shall bear adequate directions for use to provide that beverages prepared therefrom shall contain no more than 0.2 percent glycine.

§ 172.814 Hydroxylated lecithin.

The food additive hydroxylated lecithin may be safely used as an emulsifier in foods in accordance with the following conditions:

(a) The additive is obtained by the treatment of lecithin in one of the following ways, under controlled conditions whereby the separated fatty acid fraction of the resultant product has an acetyl value of 30 to 38:

(1) With hydrogen peroxide, benzoyl peroxide, lactic acid, and sodium hydroxide.

(2) With hydrogen peroxide, acetic acid, and sodium hydroxide.

(b) It is used or intended for use, in accordance with good manufacturing practice, as an emulsifier in foods, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive, the label of the food additive container shall bear, in addition to the other information required by the act:

(1) The name of the additive, "hydroxylated lecithin".

(2) Adequate directions for its use.

§ 172.816 Methyl glucoside-coconut oil ester.

Methyl glucoside-coconut oil ester may be safely used in food in accordance with the following conditions:

(a) It is the methyl glucoside-coconut oil ester having the following specifications:

Acid number	10–20.
Hydroxyl number	200–300.
pH (5% aqueous)	4.8–5.0.
Saponification number	178–190.

(b) It is used or intended for use as follows:

(1) As an aid in crystallization of sucrose and dextrose at a level not to exceed the minimum quantity required to produce its intended effect.

(2) As a surfactant in molasses at a level not to exceed 320 parts per million in the molasses.

§ 172.818 Oxystearin.

The food additive oxystearin may be safely used in foods, when such use is not precluded by standards of identity in accordance with the following conditions.

(a) The additive is a mixture of the glycerides of partially oxidized stearic and other fatty acids obtained by heating hydrogenated cottonseed or soybean oil under controlled conditions, in the presence of air and a suitable catalyst which is not a food additive as so defined. The resultant product meets the following specifications:

Acid number	Maximum 15.
Iodine number	Maximum 15.
Saponification number	225–240.
Hydroxyl number	30–45.
Unsaponifiable material	Maximum 0.8 percent.
Refractive index (butyro)	60 ± 1 at 48° C.

(b) It is used or intended for use as a crystallization inhibitor in vegetable oils and as a release agent in vegetable oils and vegetable shortenings, whereby the additive does not exceed 0.125 percent of the combined weight of the oil or shortening.

(c) To insure safe use of the additive, the label and labeling of the additive container shall bear, in addition to the other information required by the act:

(1) The name of the additive.

(2) Adequate directions to provide an oil or shortening that complies with the limitations prescribed in paragraph (b) of this section.

§ 172.820 Polyethylene glycol (mean molecular weight 200–9,500).

Polyethylene glycol identified in this section may be safely used in food in accordance with the following prescribed conditions:

(a) *Identity.* (1) The additive is an addition polymer of ethylene oxide and water with a mean molecular weight of 200 to 9,500.

(2) It contains no more than 0.2 percent total by weight of ethylene and diethylene glycols when tested by the analytical methods prescribed in paragraph (b) of this section.

(b) *Analytical method.* (1) The analytical method prescribed in the U.S.P. XVII for polyethylene glycol 400 shall be used to determine the total ethylene and diethylene glycol content of polyethylene glycols having mean molecular weights of 450 or higher.

(2) The following analytical method shall be used to determine the total ethylene and diethylene glycol content of polyethylene glycols having mean molecular weights below 450.

ANALYTICAL METHOD

ETHYLENE GLYCOL AND DIETHYLENE GLYCOL CONTENT OF POLYETHYLENE GLYCOLS

The analytical method for determining ethylene glycol and diethylene glycol is as follows:

APPARATUS

Gas chromatograph with hydrogen flame ionization detector (Varian Aerograph 600 D or equivalent). The following conditions shall be employed with the Varian Aerograph 600 D gas chromatograph:

Column temperature: 165° C.

Inlet temperature: 260° C.

Carrier gas (nitrogen) flow rate: 70 milliliters per minute.

Hydrogen and air flow to burner: Optimize to give maximum sensitivity.

Sample size: 2 microliters.

Elution time: Ethylene glycol: 2.0 minutes. Diethylene glycol: 6.5 minutes.

Recorder: −0.5 to +1.05 millivolt, full span, 1 second full response time.

Syringe: 10-microliter (Hamilton 710 N or equivalent).

Chromatograph column: 5 feet x ⅛ inch. I.D. stainless steel tube packed with sorbitol (Mathieson-Coleman-Bell 2768 Sorbitol SX850, or equivalent) 12 percent in H_2O by weight on 60–80 mesh nonacid washed diatomaceous earth (Chromosorb W. Johns-Manville, or equivalent).

REAGENTS AND MATERIALS

Carrier gas, nitrogen: Commercial grade in cylinder equipped with reducing regulator to provide 50 p.s.i.g. to the gas chromatograph.

Ethylene glycol: Commercial grade. Purify if necessary, by distillation.

Diethylene glycol: Commercial grade. Purify, if necessary, by distillation.

Glycol standards: Prepare chromatographic standards by dissolving known amounts of ethylene glycol and diethylene glycol in water. Suitable concentrations for standardization range from 1 to 6 milligrams of each component per milliliter (for example 10 milligrams diluted to volume in a 10-milliliter volumetric flask is equivalent to 1 milligram per milliliter).

STANDARDIZATION

Inject a 2-microliter aliquot of the glycol standard into the gas chromatograph employing the conditions described above. Measure the net peak heights for the ethylene gly-

[11] Copies may be obtained from: The National Academy of Sciences, 2101 Constitution Ave. NW., Washington, D.C. 20037.

col and for the diethylene glycol. Record the values as follows:

A=Peak height in millimeters of the ethylene glycol peak.

B=milligrams of ethylene glycol per milliliter of standard solution.

C=Peak height in millimeters of the diethylene glycol peak.

D=Milligrams of diethylene glycol per milliliter of standard solution.

PROCEDURE

Weigh approximately 4 grams of polyethylene glycol sample accurately into a 10-milliliter volumetric flask. Dilute to volume with water. Mix the solution thoroughly and inject a 2-microliter aliquot into the gas chromatograph. Measure the heights, in millimeters, of the ethylene glycol peak and of the diethylene glycol peak and record as E and F, respectively.

$$\text{Percent ethylene glycol} = \frac{E \times B}{A \times \text{sample weight in grams}}$$

$$\text{Percent diethylene glycol} = \frac{F \times D}{C \times \text{sample weight in grams}}$$

(c) *Uses.* It may be used, except in milk or preparations intended for addition to milk, as follows:

(1) As a coating, binder, plasticizing agent, and/or lubricant in tablets used for food.

(2) As an adjuvant to improve flavor and as a bodying agent in nonnutritive sweeteners identified in § 180.37 of this chapter.

(3) As an adjuvant in dispersing vitamin and/or mineral preparations.

(4) As a coating on sodium nitrite to inhibit hygroscopic properties.

(d) *Limitations.* (1) It is used in an amount not greater than that required to produce the intended physical or technical effect.

(2) A tolerance of zero is established for residues of polyethylene glycol in milk.

§ 172.822 Sodium lauryl sulfate.

The food additive sodium lauryl sulfate may be safely used in food in accordance with the following conditions:

(a) The additive meets the following specifications:

(1) It is a mixture of sodium alkyl sulfates consisting chiefly of sodium lauryl sulfate [$CH_3(CH_2)_{10}CH_2OSO_3Na$].

(2) It has a minimum content of 90 percent sodium alkyl sulfates.

(b) It is used or intended for use:

(1) As an emulsifier in or with egg whites whereby the additive does not exceed the following limits:

Egg white solids, 1,000 parts per million.
Frozen egg whites, 125 parts per million.
Liquid egg whites, 125 parts per million.

(2) As a whipping agent at a level not to exceed 0.5 percent by weight of gelatine used in the preparation of marshmallows.

(3) As a surfactant in:

(i) Fumaric acid-acidulated dry beverage base whereby the additive does not exceed 25 parts per million of the finished beverage and such beverage base is not for use in a food for which a standard of identity established under section 401 of the act precludes such use.

(ii) Fumaric acid-acidulated fruit juice drinks whereby the additive does not exceed 25 parts per million of the finished fruit juice drink and it is not used in a fruit juice drink for which a standard of identity established under section 401 of the act precludes such use.

(c) To insure the safe use of the additive, the label of the food additive container shall bear, in addition to the other information required by the act:

(1) The name of the additive, sodium lauryl sulfate.

(2) Adequate use directions to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

§ 172.824 Sodium mono- and dimethyl naphthalene sulfonates.

The food additive sodium mono- and dimethyl naphthalene sulfonates may be safely used in accordance with the following prescribed conditions:

(a) The additive has a molecular weight range of 245–260.

(b) The additive is used or intended for use:

(1) In the crystallization of sodium carbonate in an amount not to exceed 250 parts per million of the sodium carbonate. Such sodium carbonate is used or intended for use in potable water systems to reduce hardness and aid in sedimentation and coagulation by raising the pH for the efficient utilization of other coagulation materials.

(2) As an anticaking agent in sodium nitrite at a level not in excess of 0.1 percent by weight thereof for authorized uses in cured fish and meat.

(3) In the washing or to assist in the lye peeling of fruits and vegetables as prescribed in § 173.315 of this chapter.

(c) In addition to the general labeling requirements of the act:

(1) Sodium carbonate produced in accordance with paragraph (b)(1) of this section shall be labeled to show the presence of the additive and its label or labeling shall bear adequate directions for use.

(2) Sodium nitrite produced in accordance with paragraph (b)(2) of this section shall bear the labeling required by § 172.175 and a statement declaring the presence of sodium mono- and dimethyl naphthalene sulfonates.

§ 172.826 Sodium stearyl fumarate.

Sodium stearyl fumarate may be safely used in food in accordance with the following conditions:

(a) It contains not less than 99 percent sodium stearyl fumarate calculated on the anhydrous basis; and not more than 0.25 percent sodium stearyl maleate.

(b) The additive is used or intended for use:

(1) As a dough conditioner in yeast-leavened bakery products in an amount not to exceed 0.5 percent by weight of the flour used.

(2) As a conditioning agent in dehydrated potatoes in an amount not to exceed 1 percent by weight thereof.

(3) As a stabilizing agent in nonyeast-leavened bakery products in an amount not to exceed 1 percent by weight of the flour used.

(4) As a conditioning agent in processed cereals for cooking in an amount not to exceed 1 percent by weight of the dry cereal, except for foods for which standards of identity preclude such use.

(5) As a conditioning agent in starch-thickened or flour-thickened foods in an amount not to exceed 0.2 percent by weight of the food.

§ 172.828 Acetylated monoglycerides.

The food additive acetylated monoglycerides may be safely used in or on food in accordance with the following prescribed conditions:

(a) The additive is manufactured by:

(1) The interesterification of edible fats with triacetin and in the presence of catalytic agents that are not food additives or are authorized by regulation, followed by a molecular distillation or by steam stripping; or

(2) The direct acetylation of edible monoglycerides with acetic anhydride without the use of catalyst or molecular distillation, and with the removal by vacuum distillation, if necessary, of the acetic acid, acetic anhydride, and triacetin.

(b) The food additive has a Reichert-Meissl value of 75–150 and an acid value of less than 6.

(c) The food additive is used at a level not in excess of the amount reasonably required to produce its intended effect in food, or in food-processing, food-packing, or food-storage equipment.

§ 172.830 Succinylated monoglycerides.

The food additive succinylated monoglycerides may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a mixture of semi- and neutral succinic acid esters of mono- and diglycerides produced by the succinylation of a product obtained by the glycerolysis of edible fats and oils, or by the direct esterification of glycerol with edible fat-forming fatty acids.

(b) The additive meets the following specifications:

Succinic acid content	14.8%–25.6%.
Melting point	50° C–60° C.
Acid number	70–120.

(c) The additive is used or intended for use in the following foods:

(1) As an emulsifier in liquid and plastic shortenings at a level not to exceed 3 percent by weight of the shortening.

(2) As a dough conditioner in bread baking, when such use is permitted by an appropriate food standard, at a level not to exceed 0.5 percent by weight of the flour used.

§ 172.832 Monoglyceride citrate.

A food additive that is a mixture of glyceryl monooleate and its citric acid

monoester manufactured by the reaction of glyceryl monooleate with citric acid under controlled conditions may be safely used as a synergist and solubilizer for antioxidants in oils and fats, when used in accordance with the conditions prescribed in this section.

(a) The food additive meets the following specifications:

Acid number, 70–100.
Total citric acid (free and combined), 14 percent–17 percent.

(b) It is used, or intended for use, in antioxidant formulations for addition to oils and fats whereby the additive does not exceed 200 parts per million of the combined weight of the oil or fat and the additive.

(c) To assure safe use of the additive:

(1) The container label shall bear, in addition to the other information required by the act, the name of the additive.

(2) The label or accompanying labeling shall bear adequate directions for the use of the additive which, if followed, will result in a food that complies with the requirements of this section.

§ 172.834 Ethoxylated mono- and diglycerides.

The food additive ethoxylated mono- and diglycerides (polyoxyethylene (20) mono- and diglycerides of fatty acids) (polyglycerate 60) [Chemical Abstracts Service Registry No. 977051–30–1] may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by:

(1) Glycerolysis of edible fats primarily composed of stearic, palmitic, and myristic acids; or

(2) Direct esterification of glycerol with a mixture of primarily stearic, palmitic, and myristic acids;

to yield a product with less than 0.3 acid number and less than 0.2 percent water, which is then reacted with ethylene oxide.

(b) The additive meets the following specifications:

Saponification number, 65–75.
Acid number, 0–2.
Hydroxyl number, 65–80.
Oxyethylene content, 60.5–65.0 percent.

(c) The additive is used or intended for use in the following foods when standards of identity established under section 401 of the act do not preclude such use:

Use	*Limitations*
1. As a dough conditioner in yeast-leavened bakery products.	Not to exceed 0.5 percent by weight of the flour used.
2. As an emulsifier in cakes and cake mixes.	Not to exceed 0.5 percent by weight of the dry ingredients.
3. As an emulsifier in whipped vegetable oil toppings and topping mixes.	Not to exceed 0.45 percent by weight of the finished whipped vegetable oil toppings.
4. As an emulsifier in icings and icing mixes.	Not to exceed 0.5 percent by weight of the finished icings.
5. As an emulsifier in frozen desserts.	Not to exceed 0.2 percent by weight of the finished frozen dessert.
6. As an emulsifier in edible vegetable fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee.	Not to exceed 0.4 percent by weight of the finished vegetable fat-water emulsions.

(d) When the name "polyglycerate 60" is used in labeling it shall be followed by either "polyoxyethylene (20) mono- and diglycerides of fatty acids" or "ethoxylated mono- and diglycerides" in parentheses.

§ 172.836 Polysorbate 60.

The food additive polysorbate 60 (polyoxyethylene (20) sorbitan monostearate) which is a mixture of polyoxyethylene ethers of mixed partial stearic and palmitic acid esters of sorbitol anhydrides and related compounds, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting stearic acid (usually containing associated fatty acids, chiefly palmitic) with sorbitol to yield a product with a maximum acid number of 10 and a maximum water content of 0.2 percent, which is then reacted with ethylene oxide.

(b) The food additive meets the following specifications:

Saponification number 45–55.
Acid number 0–2.
Hydroxyl number 81–96.
Oxyethylene content 65 percent–69.5 percent.

(c) It is used or intended for use as follows:

(1) As an emulsifier in whipped vegetable oil topping with or without one or a combination of the following:

(i) Sorbitan monostearate;
(ii) Polysorbate 65;
(iii) Polysorbate 80;

whereby the maximum amount of the additive or additives used does not exceed 0.4 percent of the weight of the finished whipped vegetable oil topping; except that a combination of the additive with sorbitan monostearate may be used in excess of 0.4 percent, provided that the amount of the additive does not exceed 0.77 percent and the amount of sorbitan monostearate does not exceed 0.27 percent of the weight of the finished whipped vegetable oil topping.

(2) As an emulsifier in cakes and cake mixes, with or without one or a combination of the following:

(i) Polysorbate 65.
(ii) Sorbitan monostearate.

When used alone, the maximum amount of polysorbate 60 shall not exceed 0.46 percent of the cake or cake mix, on a dry-weight basis. When used with polysorbate 65 and/or sorbitan monostearate, it shall not exceed 0.46 percent, nor shall the polysorbate 65 exceed 0.32 percent or the sorbitan monostearate exceed 0.61 percent, and no combination of these emulsifiers shall exceed 0.66 percent of the cake or cake mix, all calculated on a dry-weight basis.

(3) As an emulsifier, alone or in combination with sorbitan monostearate, in nonstandardized confectionery coatings and standardized cacao products specified in §§ 163.123, 163.130, 163.135, 163.140, 163.145, and 163.150 of this chapter, as follows:

(i) It is used alone in an amount not to exceed 0.5 percent of the weight of the finished nonstandardized confectionery coating or standardized cacao product.

(ii) It is used with sorbitan monostearate in any combination of up to 0.5 percent of polysorbate 60 and up to 1 percent of sorbitan monostearate: *Provided*, That the total combination does not exceed 1 percent of the weight of the finished nonstandardized confectionery coating or standardized cacao product.

(4) [Reserved]

(5) As an emulsifier in cake icings and cake fillings, with or without one or a combination of the following:

(i) Polysorbate 65.
(ii) Sorbitan monostearate.

When used alone, the maximum amount of polysorbate 60 shall not exceed 0.46 percent of the weight of the cake icings and cake fillings. When used with polysorbate 65 and/or sorbitan monostearate, it shall not exceed 0.46 percent, nor shall the polysorbate 65 exceed 0.32 percent or the sorbitan monostearate exceed 0.7 percent, and no combination of these emulsifiers shall exceed 1 percent of the weight of the cake icing or cake filling.

(6) To impart greater opacity to sugar-type confection coatings whereby the maximum amount of the additive does not exceed 0.2 percent of the weight of the finished sugar coating.

(7) As an emulsifier in nonstandardized dressings whereby the maximum amount of the additive does not exceed 0.3 percent of the weight of the finished dressings.

(8) As an emulsifier, alone or in combination with polysorbate 80, in shortenings and edible oils intended for use in nonstandardized baked goods, baking mixes, icings, fillings, and toppings, and in the frying of foods, as follows:

(i) It is used alone in an amount not to exceed 1 percent of the weight of the finished shortening or oil.

(ii) It is used with polysorbate 80 in any combination providing no more than 1 percent of polysorbate 60 and no more than 1 percent of polysorbate 80, provided that the total combination does not exceed 1 percent of the finished shortening or oil.

(iii) The 1-percent limitation specified in paragraph (c)(8) (i) and (ii) of this section may be exceeded in premix concentrates of shortening or edible oil if the labeling complies with the requirements of paragraph (d) of this section.

(9) As an emulsifier in solid-state, edible vegetable fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee, with or without one or a combination of the following:

(i) Polysorbate 65.

(ii) Sorbitan monostearate.

The maximum amount of the additive or additives shall not exceed 0.4 percent by weight of the finished edible vegetable fat-water emulsion.

(10) As a foaming agent in nonalcoholic mixes, to be added to alcoholic beverages in the preparation of mixed alcoholic drinks, at a level not to exceed 4.5 percent by weight of the nonalcoholic mix.

(11) As a dough conditioner in yeast-leavened bakery products in an amount not to exceed 0.5 percent by weight of the flour used.

(12) As an emulsifier, alone or in combination with sorbitan monostearate, in the minimum quantity required to accomplish the intended effect, in formulations of white mineral oil conforming with § 172.878 and/or petroleum wax conforming with § 172.886 for use as protective coatings on raw fruits and vegetables.

(13) As a dispersing agent in artificially sweetened gelatin desserts and in artificially sweetened gelatin dessert mixes, whereby the amount of the additive does not exceed 0.5 percent on a dry-weight basis.

(14) As an emulsifier in chocolate flavored syrups, whereby the maximum amount of the additive does not exceed 0.05 percent in the finished product.

(d) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label of the additive and any intermediate premixes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

§ 172.838 Polysorbate 65.

The food additive polysorbate 65 (polyoxyethylene (20) sorbitan tristearate), which is a mixture of polyoxyethylene ethers of mixed stearic acid esters of sorbitol anhydrides and related compounds, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting stearic acid (usually containing associated fatty acids, chiefly palmitic) with sorbitol to yield a product with a maximum acid number of 15 and a maximum water content of 0.2 percent, which is then reacted with ethylene oxide.

(b) The food additive meets the following specifications:

Saponification number 88–98.
Acid number 0–2.
Hydroxyl number 44–60.
Oxyethylene content 46 percent–50 percent.

(c) The additive is used, or intended for use, as follows:

(1) As an emulsifier in ice cream, frozen custard, ice milk, fruit sherbet and nonstandardized frozen desserts when used alone or in combination with polysorbate 80, whereby the maximum amount of the additives, alone or in combination, does not exceed 0.1 percent of the finished frozen dessert.

(2) As an emulsifier in cakes and cake mixes, with or without one or a combination of the following:

(i) Sorbitan monostearate.

(ii) Polysorbate 60.

When used alone, the maximum amount of polysorbate 65 shall not exceed 0.32 percent of the cake or cake mix, on a dry-weight basis. When used with sorbitan monostearate and/or polysorbate 60, it shall not exceed 0.32 percent, nor shall the sorbitan monostearate exceed 0.61 percent or the polysorbate 60 exceed 0.46 percent, and no combination of these emulsifiers shall exceed 0.66 percent of the cake or cake mix, all calculated on a dry-weight basis.

(3) As an emulsifier in whipped vegetable oil topping with or without one or a combination of the following:

(i) Sorbitan monostearate;

(ii) Polysorbate 60;

whereby the maximum amount of the additive or additives used does not exceed 0.4 percent of the weight of the finished whipped vegetable oil topping.

(iii) Polysorbate 80;

(4) As an emulsifier in solid-state, edible vegetable fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee, with or without one or a combination of the following:

(i) Sorbitan monostearate.

(ii) Polysorbate 60.

The maximum amount of the additive or additives shall not exceed 0.4 percent by weight of the finished edible vegetable fat-water emulsion.

(5) As an emulsifier in cake icings and cake fillings, with or without one or a combination of the following:

(i) Sorbitan monostearate.

(ii) Polysorbate 60.

When used alone, the maximum amount of polysorbate 65 shall not exceed 0.32 percent of the weight of the cake icing or cake filling. When used with sorbitan monostearate and/or polysorbate 60, it shall not exceed 0.32 percent, nor shall the sorbitan monostearate exceed 0.7 percent or the polysorbate 60 exceed 0.46 percent, and no combination of these emulsifiers shall exceed 1 percent of the weight of the cake icing or cake filling.

(d) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label of the additive and any intermediate premixes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

§ 172.840 Polysorbate 80.

The food additive polysorbate 80 (polyoxyethylene (20) sorbitan monooleate), which is a mixture of polyoxyethylene ethers of mixed partial oleic acid esters of sorbitol anhydrides and related compounds, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting oleic acid (usually containing associated fatty acids) with sorbitol to yield a product with a maximum acid number of 7.5 and a maximum water content of 0.5 percent, which is then reacted with ethylene oxide.

(b) The food additive meets the following specifications:

Saponification number 45–55.
Acid number 0–2.
Hydroxyl number 65–80.
Oxyethylene content 65 percent–69.5 percent.

(c) The additive is used or intended for use as follows:

(1) An emulsifier in ice cream, frozen custard, ice milk, fruit sherbet, and nonstandardized frozen desserts, when used alone or in combination with polysorbate 65 whereby the maximum amount of the additives, alone or in combination, does not exceed 0.1 percent of the finished frozen dessert.

(2) In yeast-defoamer formulations, whereby the maximum amount of the additive does not exceed 4 percent of the finished yeast defoamer and the maximum amount of the additive in the yeast from such use does not exceed 4 parts per million.

(3) As a solubilizing and dispersing agent in pickles and pickle products, whereby the maximum amount of the additive does not exceed 500 parts per million.

(4) As a solubilizing and dispersing agent in:

(i) Vitamin-mineral preparations containing calcium caseinate in the absence of fat-soluble vitamins, whereby the maximum intake of polysorbate 80 shall not exceed 175 milligrams from the recommended daily dose of the preparations.

(ii) Fat-soluble vitamins in vitamin and vitamin-mineral preparations containing no calcium caseinate, whereby the maximum intake of polysorbate 80 shall not exceed 300 milligrams from the recommended daily dose of the preparations.

(iii) In vitamin-mineral preparations containing both calcium caseinate and fat-soluble vitamins, whereby the maximum intake of polysorbate 80 shall not exceed 475 milligrams from the recommended daily dose of the preparations.

(5) As a surfactant in the production of coarse crystal sodium chloride whereby the maximum amount of the additive in the finished sodium chloride does not exceed 10 parts per million.

(6) In special dietary foods, as an emulsifier for edible fats and oils, with directions for use which provide for the ingestion of not more than 360 milligrams of polysorbate 80 per day.

(7) As a solubilizing and dispersing agent for dill oil in canned spiced green beans, not to exceed 30 parts per million.

(8) As an emulsifier, alone or in combination with polysorbate 60, in shortenings and edible oils intended for use in nonstandardized baked goods, baking mixes, icings, fillings, and toppings and in the frying of foods, as follows:

(i) It is used alone in an amount not to exceed 1 percent of the weight of the finished shortening or oil.

(ii) It is used with polysorbate 60 in any combination providing no more than 1 percent of polysorbate 80 and no more than 1 percent of polysorbate 60, provided that the total combination does not exceed 1 percent of the finished shortening or oil.

(iii) The 1-percent limitation specified in paragraph (c)(8) (i) and (ii) of this section may be exceeded in premix concentrates of shortening or edible oil if the labeling complies with the requirements of paragraph (d) of this section.

(9) As an emulsifier in whipped vegetable oil topping with or without one or a combination of the following:

(i) Sorbitan monostearate;

(ii) Polysorbate 60.

(iii) Polysorbate 65.

whereby the maximum amount of the additive or additives used does not exceed 0.4 percent of the weight of the finished whipped vegetable oil topping.

(10) It is used as a wetting agent in scald water for poultry defeathering, followed by potable water rinse. The concentration of the additive in the scald water does not exceed 0.0175 percent.

(11) As a dispersing agent in gelatin desserts and in gelatin dessert mixes, whereby the amount of the additive does not exceed 0.082 percent on a dry-weight basis.

(12) As an adjuvant added to herbicide use and plant-growth regulator use dilutions by a grower or applicator prior to application of such dilutions to the growing crop. Residues resulting from such use are exempt from the requirement of a tolerance. When so used or intended for use, the additive shall be exempt from the requirements of paragraph (d)(1) of this section.

(13) As a defoaming agent in the preparation of the creaming mixture for cottage cheese and lowfat cottage cheese, as identified in §§ 133.128 and 133.131 of this chapter, respectively, whereby the amount of the additive does not exceed .008 percent by weight of the finished products.

(d) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label of the additive and any intermediate premixes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

§ 172.842 Sorbitan monostearate.

The food additive sorbitan monostearate, which is a mixture of partial stearic and palmitic acid esters of sorbitol anhydrides, may be safely used in or on food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting stearic acid (usually containing associated fatty acids, chiefly palmitic) with sorbitol to yield essentially a mixture of esters.

(b) The food additive meets the following specifications:

Saponification number	147–157
Acid number	5–10
Hydroxyl number	235–260

(c) It is used or intended for use, alone or in combination with polysorbate 60 as follows:

(1) As an emulsifier in whipped vegetable oil topping with or without one or a combination of the following:

(i) Polysorbate 60;

(ii) Polysorbate 65;

(iii) Polysorbate 80;

whereby the maximum amount of the additive or additives used does not exceed 0.4 percent of the weight of the finished whipped vegetable oil topping; except that a combination of the additive with polysorbate 60 may be used in excess of 0.4 percent: *Provided*, That the amount of the additive does not exceed 0.27 percent and the amount of polysorbate 60 does not exceed 0.77 percent of the weight of the finished whipped vegetable oil topping.

(2) As an emulsifier in cakes and cake mixes, with or without one or a combination of the following:

(i) Polysorbate 65.

(ii) Polysorbate.

When used alone, the maximum amount of sorbitan monostearate shall not exceed 0.61 percent of the cake or cake mix, on a dry-weight basis. When used with polysorbate 65 and/or polysorbate 60, it shall not exceed 0.61 percent, nor shall the polysorbate 65 exceed 0.32 percent or the polysorbate 60 exceed 0.46 percent, and no combination of the emulsifiers shall exceed 0.66 percent of the weight of the cake or cake mix, calculated on a dry-weight basis.

(3) As an emulsifier, alone or in combination with polysorbate 60 in nonstandardized confectionery coatings and standardized cacao products specified in §§ 163.123, 163.130, 163.135, 163.140, 163.145, and 163.150 of this chapter, as follows:

(i) It is used alone in an amount not to exceed 1 percent of the weight of the finished nonstandardized confectionery coating or standardized cacao product.

(ii) It is used with polysorbate 60 in any combination of up to 1 percent sorbitan monostearate and up to 0.5 percent polysorbate 60 provided that the total combination does not exceed 1 percent of the weight of the finished nonstandardized confectionery coating or standardized cacao product.

(4) As an emulsifier in cake icings and cake fillings, with or without one or a combination of the following:

(i) Polysorbate 65.

(ii) Polysorbate 60.

When used alone, the maximum amount of sorbitan monostearate shall not exceed 0.7 percent of the weight of the cake icing or cake filling. When used with polysorbate 65 and/or polysorbate 60, it shall not exceed 0.7 percent, nor shall the polysorbate 65 exceed 0.32 percent or the polysorbate 60 exceed 0.46 percent, and no combination of these emulsifiers shall exceed 1 percent of the weight of the cake icing or cake filling.

(5) As an emulsifier in solid-state, edible vegetable fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee, with or without one or a combination of the following:

(i) Polysorbate 60.

(ii) Polysorbate 65.

The maximum amount of the additive or additives shall not exceed 0.4 percent by weight of the finished edible vegetable fat-water emulsion.

(6) It is used alone as a rehydration aid in the production of active dry yeast in an amount not to exceed 1 percent by weight of the dry yeast.

(7) As an emsulsifier, alone or in combination with polysorbate 60, in the minimum quantity required to accomplish the intended effect, in formulations of white mineral oil conforming with § 172.878 and/or petroleum wax conforming with § 172.886 for use as protective coatings on raw fruits and vegetables.

(d) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label of the additive and any intermediate premixes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

§ 172.844 Calcium stearoyl-2-lactylate.

The food additive calcium stearoyl-2-lactylate may be safely used in or on food in accordance with the following prescribed conditions:

(a) The additive, which is a mixture of calcium salts of stearoyl lactylic acids and minor proportions of other calcium salts of related acids, is manufactured by the reaction of stearic acid and lactic acid and conversion to the calcium salts.

(b) The additive meets the following specifications:

Acid number, 50–86.
Calcium content, 4.2–5.2 percent.
Lactic acid content, 32–38 percent.
Ester number, 125–164.

(c) It is used or intended for use as follows:

(1) As a dough conditioner in yeast-leavened bakery products and prepared mixes for yeast-leavened bakery products in an amount not to exceed 0.5 part

for each 100 parts by weight of flour used.

(2) As a whipping agent in:

(i) Liquid and frozen egg white at a level not to exceed 0.05 percent.

(ii) Dried egg white at a level not to exceed 0.5 percent.

(iii) Whipped vegetable oil topping at a level not to exceed 0.3 percent of the weight of the finished whipped vegetable oil topping.

(3) As a conditioning agent in dehydrated potatoes in an amount not to exceed 0.5 percent by weight thereof.

(d) To assure safe use of the additive:

(1) The label and labeling of the food additive and any intermediate premix prepared therefrom shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive.

(ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling of the food additive shall also bear adequate directions of use to provide a finished food that complies with the limitations prescribed in paragraph (c) of this section.

§ 172.846 Sodium stearoyl-2-lactylate.

The food additive sodium stearoyl-2-lactylate may be safely used in food in accordance with the following prescribed conditions:

(a) The additive, which is a mixture of sodium salts of stearoyl lactylic acids and minor proportions of other sodium salts of related acids, is manufactured by the reaction of stearic acid and lactic acid and conversion to the sodium salts.

(b) The additive meets the following specifications:

Acid number, 60–80.
Sodium content, 3.5 percent–5.0 percent.
Lactic acid content, 31 percent–34 percent.
Ester number, 150–190.

(c) It is used or intended for use as an emulsifier, dough conditioner, or whipping agent in the following foods when standards of identity established under section 401 of the act do not preclude such use: Icings, fillings, puddings, and toppings; baked products; pancakes and waffles; prepared mixes for any of the foregoing foods; and in liquid and solid edible vegetable fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee.

(d) It is used in an amount not greater than required to produce the intended physical or technical effect.

§ 172.848 Lactylic esters of fatty acids.

Lactylic esters of fatty acids may be safely used in food in accordance with the following prescribed conditions:

(a) They are prepared from lactic acid and fatty acids meeting the requirements of § 172.860(b) and/or oleic acid derived from tall oil fatty acids meeting the requirements of § 172.862.

(b) They are used as emulsifiers, plasticizers, or surface-active agents in the following foods, when standards of identity do not preclude their use:

Foods	Limitations
Bakery mixes	
Baked products	
Cake icings, fillings, and toppings.	
Dehydrated fruits and vegetables.	
Dehydrated fruit and vegetable juices.	
Edible vegetable fat-water emulsions.	As substitutes for milk or cream in beverage coffee.
Frozen desserts	
Liquid shortening	For household use.
Pancake mixes	
Precooked instant rice	
Pudding mixes	

(c) They are used in an amount not greater than required to produce the intended physical or technical effect, and they may be used with shortening and edible fats and oils when such are required in the foods identified in paragraph (b) of this section.

§ 172.850 Lactylated fatty acid esters of glycerol and propylene glycol.

The food additive lactylated fatty acid esters of glycerol and propylene glycol may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a mixture of esters produced by the lactylation of a product obtained by reacting edible fats or oils with propylene glycol.

(b) The additive meets the following specifications: Water insoluble combined lactic acid, 14–18 percent; and acid number, 12 maximum.

(c) It is used in amounts not in excess of that reasonably required to produce the intended physical effect as an emulsifier, plasticizer, or surface-active agent in food.

§ 172.852 Glyceryl-lacto esters of fatty acids.

Glyceryl-lacto esters of fatty acids (the lactic acid esters of mono- and diglycerides) may be safely used in food in accordance with the following prescribed conditions:

(a) They are manufactured from glycerin, lactic acid, and fatty acids conforming with § 172.860 and/or oleic acid derived from tall oil fatty acids conforming with § 172.862 and/or edible fats and oils.

(b) They are used in amounts not in excess of those reasonably required to accomplish their intended physical or technical effect as emulsifiers and plasticizers in food.

§ 172.854 Polyglycerol esters of fatty acids.

Polyglycerol esters of fatty acids, up to and including the decaglycerol esters, may be safely used in food in accordance with the following prescribed conditions:

(a) They are prepared from corn oil, cottonseed oil, lard, palm oil from fruit, peanut oil, safflower oil, sesame oil, soybean oil, and tallow and the fatty acids derived from these substances (hydrogenated and nonhydrogenated) meeting the requirements of § 172.860(b) and/or oleic acid derived from tall oil fatty acids meeting the requirements of § 172.862.

(b) They are used as emulsifiers in food, in amounts not greater than that required to produce the intended physical or technical effect.

(c) Polyglycerol esters of a mixture of stearic, oleic, and coconut fatty acids are used as a cloud inhibitor in vegetable and salad oils when use is not precluded by standards of identity. The fatty acids used in the production of the polyglycerol esters meet the requirements of § 172.860(b), and the polyglycerol esters are used at a level not in excess of the amount required to perform its cloud-inhibiting effect. Oleic acid derived from tall oil fatty acids conforming with § 172.862 may be used as a substitute for or together with the oleic acid permitted by this paragraph.

(d) Polyglycerol esters of butter oil fatty acids are used as emulsifiers in combination with other approved emulsifiers in dry, whipped topping base. The fatty acids used in the production of the polyglycerol esters meet the requirements of § 172.860(b), and the polyglycerol esters are used at a level not in excess of the amount required to perform their emulsifying effect.

§ 172.856 Propylene glycol mono- and diesters of fats and fatty acids.

Propylene glycol mono- and diesters of fats and fatty acids may be safely used in food, subject to the following prescribed conditions:

(a) They are produced from edible fats and/or fatty acids in compliance with § 172.860 and/or oleic acid derived from tall oil fatty acids in compliance with § 172.862.

(b) They are used in food in amounts not in excess of that reasonably required to produce their intended effect.

§ 172.858 Propylene glycol alginate.

The food additive propylene glycol alginate may be used as an emulsifier, stabilizer, or thickener in foods in accordance with the following prescribed conditions:

(a) The additive is the ester of alginic acid and propylene glycol, containing up to 85 percent of the carboxylic acid groups esterified with the remaining groups either free or neutralized.

(b) It is used or intended for use as a stabilizer in ice cream, frozen custard, ice milk, fruit sherbet, and water ices at not to exceed 0.5 percent of the weight of the finished product, and is used or intended for use, in accordance with good manufacturing practice, as an emulsifier, stabilizer, or thickener in foods except for those standardized foods that do not provide for such use.

(c) To insure safe use of the additive, the label of the food additive container shall bear, in addition to the other information required by the act:

(1) The name of the additive, "propylene glycol alginate" or "propylene glycol ester of alginic acid".

(2) Adequate directions for use.

§ 172.860 Fatty acids.

The food additive fatty acids may be safely used in food and in the manufacture of food components in accordance with the following prescribed conditions:

(a) The food additive consists of one or any mixture of the following straight-chain monobasic carboxylic acids and their associated fatty acids manufactured from fats and oils derived from edible sources: Capric acid, caprylic acid, lauric acid, myristic acid, oleic acid, palmitic acid, and stearic acid.

(b) The food additive meets the following specifications:

(1) Unsaponifiable matter does not exceed 2 percent.

(2) It is free of chick-edema factor:

(i) As evidenced during the bioassay method for determining the chick-edema factor as prescribed in paragraph (c)(2) of this section; or

(ii) As evidenced by the absence of chromatographic peaks with a retention time relative to aldrin (RA) between 10 and 25, using the gas chromatographic-electron capture method prescribed in paragraph (c)(3) of this section. If chromatographic peaks are found with RA values between 10 and 25, the food additive shall meet the requirements of the bioassay method prescribed in paragraph (c)(2) of this section for determining chick-edema factor.

(c) For the purposes of this section:

(1) Unsaponifiable matter shall be determined by the method described in the most recent edition of "Official Methods of Analysis of the Association of Official Analytical Chemists." [3]

(2) Chick-edema factor shall be determined by the bioassay method described in Official Methods of Analysis of the Association of Official Analytical Chemists, 10th Edition (1965), sections 26.087 through 26.091.[4]

(3) The gas chromatographic-electron capture method for testing fatty acids for chick-edema shall be the method described in the "Journal of the Association of Official Analytical Chemists," Volume 50 (No. 1), pages 216–218 (1967),[5] or the modified method using a sulfuric acid clean-up procedure, as described in the "Journal of the Association of Official Analytical Chemists," Volume 51 (No. 2), pages 489–490 (1968).[5]

(d) It is used or intended for use as follows:

(1) In foods as a lubricant, binder, and as a defoaming agent in accordance with good manufacturing practice.

(2) As a component in the manufacture of other food-grade additives.

(e) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the act, the following:

(1) The common or usual name of the acid or acids contained therein.

(2) The words "food grade", in juxtaposition with and equally as prominent as the name of the acid.

§ 172.862 Oleic acid derived from tall oil fatty acids.

The food additive oleic acid derived from tall oil fatty acids may be safely used in food and as a component in the manufacture of food-grade additives in accordance with the following prescribed conditions:

(a) The additive consists of purified oleic acid separated from refined tall oil fatty acids.

(b) The additive meets the following specifications:

(1) Specifications prescribed in "Food Chemicals Codex" for oleic acid, except that titer (solidification point) shall not exceed 13.5° C and unsaponifiable matter shall not exceed 0.5 percent.

(2) The resin acid content does not exceed 0.01 percent as determined by ASTM Method D 1240–54 (1961).[6]

(3) The requirements for absence of chick-edema factor as prescribed in § 172.860.

(c) It is used or intended for use as follows:

(1) In foods as a lubricant, binder, and defoaming agent in accordance with good manufacturing practice.

(2) As a component in the manufacture of other food-grade additives.

(d) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the act, the following:

(1) The common or usual name of the acid.

(2) The words "food grade" in juxtaposition with and equally as prominent as the name of the acid.

§ 172.863 Salts of fatty acids.

The food additive salts of fatty acids may be safely used in food and in the manufacture of food components in accordance with the following prescribed conditions:

(a) The additive consists of one or any mixture of two or more of the aluminum, calcium, magnesium, potassium, and sodium salts of the fatty acids conforming with § 172.860 and/or oleic acid derived from tall oil fatty acids conforming with § 172.862.

(b) The food additive is used or intended for use as a binder, emulsifier, and anticaking agent in food in accordance with good manufacturing practice.

(c) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the act, the following:

(1) The common or usual name of the fatty acid salt or salts contained therein.

(2) The words "food grade", in juxtaposition with and equally as prominent as the name of the salt.

§ 172.864 Synthetic fatty alcohols.

Synthetic fatty alcohols may be safely used in food and in the synthesis of food components in accordance with the following prescribed conditions:

(a) The food additive consists of any one of the following fatty alcohols:

(1) Hexyl, octyl, decyl, lauryl, myristyl, cetyl, and stearyl; manufactured by fractional distillation of alcohols obtained by a sequence of oxidation and hydrolysis of organo-aluminums generated by the controlled reaction of low molecular weight trialkylaluminum with purified ethylene (minimum 99 percent by volume C_2H_4), and utilizing the hydrocarbon solvent as defined in paragraph (b) of this section, such that:

(i) Hexyl, octyl, decyl, lauryl, and myristyl alcohols contain not less than 99 percent of total alcohols and not less than 96 percent of straight chain alcohols. Any nonalcoholic impurities are primarily paraffins.

(ii) Cetyl and stearyl alcohols contain not less than 98 percent of total alcohols and not less than 94 percent of straight chain alcohols. Any nonalcoholic impurities are primarily paraffins.

(iii) The synthetic fatty alcohols contain no more than 0.1 weight percent of total diols as determined by a method available upon request from the Commissioner of Food and Drugs.

(2) Hexyl, octyl, and decyl; manufactured by fractional distillation of alcohols obtained by a sequence of oxidation, hydrolysis, and catalytic hydrogenation (catalyst consists of copper, chromium, and nickel) of organo-aluminums generated by the controlled reaction of low molecular weight trialkylaluminum with purified ethylene (minimum 99 percent by volume C_2H_4), and utilizing an external coolant such that these alcohols meet the specifications prescribed in paragraph (a)(1) (i) and (iii) of this section.

(b) The hydrocarbon solvent used in the process described in paragraph (a)(1) of this section is a mixture of liquid hydrocarbons essentially paraffinic in nature, derived from petroleum and refined to meet the specifications described in paragraph (b)(1) of this section when subjected to the procedures described in paragraph (b) (2) and (3) of this section.

(1) The hydrocarbon solvent meets the following specifications:

(i) Boiling-point range: 175° C–275° C.

(ii) Ultraviolet absorbance limits as follows:

Wavelength (millimicrons):	*Maximum absorbance per centimeter optical path length*
280–289	0.15
290–299	.12
300–359	.05
360–400	.02

(2) Use ASTM Method D–86 [6] to determine boiling point range.

[3] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

[4] Copies may be obtained from: American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.

(3) The analytical method for determining ultraviolet absorbance limits is as follows:

GENERAL INSTRUCTIONS

All glassware should be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure, it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of hydrocarbon solvent samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

Chromatographic tube. 450 millimeters in length (packing section), inside diameter 19 millimeters ± 1 millimeter, equipped with a wad of clean Pyrex brand filtering wool (Corning Glass Works Catalog No. 3950 or equivalent). The tube shall contain a 250-milliliter reservoir and a 2-millimeter tetrafluoroethylene polymer stopcock at the opposite end. Overall length of the tube is 670 millimeters.

Stainless steel rod. 2 feet in length, 2 to 4 millimeters in diameter.

Vacuum oven. Similar to Labline No. 3610 but modified as follows: A copper tube one-fourth inch in diameter and 13 inches in length is bent to a right angle at the 4-inch point and plugged at the opposite end; eight copper tubes one-eighth inch in diameter and 5 inches in length are silver soldered in drilled holes (one-eighth inch in diameter) to the one-fourth-inch tube, one on each side at the 5-, 7.5-, 10- and 12.5-inch points; the one-eighth-inch copper tubes are bent to conform with the inner periphery of the oven.

Beakers. 250-milliliter and 500-milliliter capacity.

Graduated cylinders. 25-milliliter, 50-milliliter, and 150-milliliter capacity.

Tuberculin syringe. 1-milliliter capacity, with 3-inch, 22-gauge needle.

Volumetric flask. 5-milliliter capacity.

Spectrophotometric cells. Fused quartz ground glass stoppered cells, optical path length in the range of 1.000 centimeter ±0.005 centimeter. With distilled water in the cells, determine any absorbance difference.

Spectrophotometer. Spectral range 250 millimicrons—400 millimicrons with spectral slit width of 2 millimicrons or less: under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Absorbance accuracy,[1] ±0.05 at 0.4 absorbance.

Wavelength repeatability, ±0.2 millimicron.

Wavelength accuracy, ±1.0 millimicron.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

REAGENTS AND MATERIALS

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane, benzene, hexane, and 1,2-dichloroethane designated in the list following this paragraph shall pass the following test:

To the specified quantity of solvent in a 250-milliliter beaker, add 1 milliliter of purified *n*-hexadecane and evaporate in the vacuum oven under a stream of nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. (To the residue from benzene add a 5-milliliter portion of purified isooctane, reevaporate, and repeat once to insure complete removal of benzene.)

Dissolve the 1 milliliter of hexadecane residue in isooctane and make to 5 milliliters volume. Determine the absorbance in the 1-centimeter path length cells compared to isooctane as reference. The absorbance of the solution of the solvent residue shall not exceed 0.02 per centimeter path length between 280 and 300 mμ and shall not exceed 0.01 per centimeter path length between 300 and 400 mμ.

Isooctane (2,2,4-trimethylpentane). Use 10 milliliters for the test described in the preceding paragraph. If necessary, isooctane may be purified by passage through a column of activated silica gel (Grade 12, Davison Chemical Co., Baltimore, Md., or equivalent).

Benzene, spectro grade (Burdick and Jackson Laboratories, Inc., Muskegon, Mich., or equivalent). Use 80 milliliters for the test. If necessary, benzene may be purified by distillation or otherwise.

Hexane, spectro grade (Burdick and Jackson Laboratories, Inc., Muskegon, Mich., or equivalent). Use 650 milliliters for the test. If necessary, hexane may be purified by distillation or otherwise.

1,2-Dichloroethane, spectro grade (Matheson, Coleman, and Bell, East Rutherford, N.J., or equivalent). Use 20 milliliters for test. If necessary, 1,2-dichloroethane may be purified by distillation.

Eluting mixtures:

1. *10 percent 1,2-dichloroethane in hexane.* Pipet 100 milliliters of 1,2-dichloroethane into a 1-liter glass-stoppered volumetric flask and adjust to volume with hexane, with mixing.

2. *40 percent benzene in hexane.* Pipet 400 milliliters of benzene into a 1-liter glass-stoppered volumetric flask and adjust to volume with hexane, with mixing.

n-Hexadecane, 99 percent olefin-free. Dilute 1.0 milliliter of *n*-hexadecane to 5 milliliters with isooctane and determine the absorbance in a 1-centimeter cell compared to isooctane as reference between 280 mμ-400 mμ. The absorbance per centimeter path length shall not exceed 0.00 in this range. If necessary, *n*-hexadecane may be purified by percolation through activated silica gel or by distillation.

Silica gel, 28–200 mesh (Grade 12, Davison Chemical Co., Baltimore, Md., or equivalent). Activate as follows: Weigh about 900 grams into a 1-gallon bottle, add 100 milliliters of de-ionized water, seal the bottle and shake and roll at intervals for 1 hour. Allow to equilibrate overnight in the sealed bottle. Activate the gel at 150° C for 16 hours, in a 2-inch x 7-inch x 12-inch porcelain pan loosely covered with aluminum foil, cool in a dessicator, transfer to a bottle and seal.

PROCEDURE

Determination of ultraviolet absorbance. Before proceeding with the analysis of a sample determine the absorbance in a 1-centimeter path cell for the reagent blank by carrying out the procedure without a sample. Record the absorbance in the wavelength range of 280 to 400 millimicrons. Typical reagent blank absorbance in this range should not exceed 0.04 in the 280 to 299 millimicron range, 0.02 in the 300 to 359 millimicron range, and 0.01 in the 360 to 400 millimicron range. If the characteristic benzene peaks in the 250 to 260 millimicron region are present, remove the benzene by the procedure described above under "Reagents and Materials," "Organic Solvents," and record absorbance again.

Transfer 50 grams of silica gel to the chromatographic tube for sample analysis. Raise and drop the column on a semisoft, clean surface for about 1 minute to settle the gel. Pour 100 milliliters of hexane into the column with the stopcock open and allow to drain to about one-half inch above the gel. Turn off the stopcock and allow the column to cool for 30 minutes. After cooling, vibrate the column to eliminate air and stir the top 1 to 2 inches with a small diameter stainless steel rod. Take care not to get the gel above the liquid and onto the sides of the column.

Weigh out 40 grams ±0.1 gram of the hydrocarbon solvent sample into a 250-milliliter beaker, add 50 milliliters of hexane, and pour the solution into the column. Rinse the beaker with 50 milliliters of hexane and add this to the column. Allow the hexane sample solution to elute into a 500-milliliter beaker until the solution is about one-half inch above the gel. Rinse the column three times with 50-milliliter portions of hexane. Allow each hexane rinse to separately elute to about one-half inch above the gel. Replace the eluate beaker (discard the hexane eluate) with a 250-milliliter beaker. Add two separate 25-milliliter portions of 10 percent 1,2-dichloroethane and allow each to separately elute as before. Finally, add 150 milliliters of 10 percent 1,2-dichloroethane for a total of 200 milliliters. When the final 10 percent 1,2-dichloroethane fraction is about one-half inch above the top of the gel bed, replace the receiving beaker (discard the 1,2-dichloroethane eluate) with a 250-milliliter beaker containing 1 milliliter of hexadecane. Adjust the elution rate to 2 to 3 milliliters per minute, add two 25-milliliter portions of 40 percent benzene and allow each to separately elute as before to within about one-half inch of the gel bed. Finally, add 150 milliliters of 40 percent benzene for a total of 200 milliliters. Evaporate the benzene in the oven with vacuum and sufficient nitrogen flow to just ripple the top of the benzene solution. When the benzene is removed (as determined by a constant volume of hexadecane) add 5 milliliters of isooctane and evaporate. Repeat once to insure complete removal of benzene. Remove the beaker and cover with aluminum foil (previously rinsed with hexane) until cool.

Quantitatively transfer the hexadecane residue to a 5-milliliter volumetric flask and dilute to volume with isooctane. Determine the absorbance of the solution in 1-centimeter path length cells between 280 and 400 millimicrons using isooctane as a reference. Correct the absorbance values for any absorbance derived from reagents as determined by carrying out the procedure without a sample. If the corrected absorbance does not exceed the limits prescribed in subparagraph (b)(1)(ii) of this section, the

[1] As determined by procedure using potassium chromate for reference standard and Circular 484, Spectrophotometry, U.S. Department of Commerce, 1949. The accuracy described in National Bureau of Standards is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons.

sample meets the ultraviolet absorbance specifications for hydrocarbon solvent.

(c) Synthetic fatty alcohols may be used as follows:

(1) As substitutes for the corresponding naturally derived fatty alcohols permitted in food by existing regulations in this part or Part 173 of this chapter provided that the use is in compliance with any prescribed limitations.

(2) As substitutes for the corresponding naturally derived fatty alcohols used as intermediates in the synthesis of food additives and other substances permitted in food.

§ 172.866 Synthetic glycerin produced by the hydrogenolysis of carbohydrates.

Synthetic glycerin produced by the hydrogenolysis of carbohydrates may be safely used in food, subject to the provisions of this section:

(a) It shall contain not in excess of 0.2 percent by weight of a mixture of butanetriols.

(b) It is used or intended for use in an amount not to exceed that reasonably required to produce its intended effect.

§ 172.868 Ethyl cellulose.

The food additive ethyl cellulose may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is a cellulose ether containing ethoxy (OC_2H_5) groups attached by an ether linkage and containing on an anhydrous basis not more than 2.6 ethoxy groups per anhydroglucose unit.

(b) It is used or intended for use as follows:

(1) As a binder and filler in dry vitamin preparations.

(2) As a component of protective coatings for vitamin and mineral tablets.

(3) As a fixative in flavoring compounds.

§ 172.870 Hydroxypropyl cellulose.

The food additive hydroxypropyl cellulose may be safely used in food, except standardized foods that do not provide for such use, in accordance with the following prescribed conditions:

(a) The additive is a cellulose ether containing propylene glycol groups attached by an ether linkage and contains, on an anhydrous basis, not more than 4.6 hydroxypropyl groups per anhydroglucose unit. The additive has a minimum viscosity of 145 centipoises for 10 percent by weight aqueous solution at 25° C.

(b) The additive is used or intended for use as an emulsifier, film former, protective colloid, stabilizer, suspending agent, or thickener, in accordance with good manufacturing practice.

§ 172.872 Methyl ethyl cellulose.

The food additive methyl ethyl cellulose may be safely used in food in accordance with the following prescribed conditions.

(a) The additive is a cellulose ether having the general formula $[C_6H_{(10-x-y)}O_5(CH_3)_x(C_2H_5)_y]_n$, where x is the number of methyl groups and y is the number of ethyl groups. The average value of x is 0.3 and the average value of y is 0.7.

(b) The additive meets the following specifications:

(1) The methoxy content shall be not less than 3.5 percent and not more than 6.5 percent, calculated as OCH_3, and the ethoxy content shall be not less than 14.5 percent and not more than 19 percent, calculated as OC_2H_5, both measured on the dry sample.

(2) The viscosity of an aqueous solution, 2.5 grams of the material in 100 milliliters of water, at 20° C, is 20 to 60 centipoises.

(3) The ash content on a dry basis has a maximum of 0.6 percent.

(c) The food additive is used as an aerating, emulsifying, and foaming agent, in an amount not in excess of that reasonably required to produce its intended effect.

§ 172.874 Hydroxypropyl methylcellulose.

The food additive hydroxypropyl methylcellulose may be safely used in food, except confectionery and except in standardized foods which do not provide for such use if:

(a) The additive complies with the definition and specifications prescribed in the National Formulary, 12th edition.

(b) It is used or intended for use as an emulsifier, film former, protective colloid, stabilizer, suspending agent, or thickener, in accordance with good manufacturing practice.

(c) To insure safe use of the additive, the container of the additive, in addition to being labeled as required by the general provisions of the act, shall be accompanied by labeling which contains adequate directions for use to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

§ 172.876 Castor oil.

The food additive castor oil may be safely used in accordance with the following conditions:

(a) The additive meets the specifications of the United States Pharmacopeia XVII.

(b) The additive is used or intended for use as follows:

Use and Limitations
Hard candy production—As a release agent and antisticking agent, not to exceed 500 parts per million in hard candy.
Vitamin and mineral tablets—As a component of protective coatings.

§ 172.878 White mineral oil.

White mineral oil may be safely used in food in accordance with the following conditions:

(a) White mineral oil is a mixture of liquid hydrocarbons, essentially paraffinic and naphthenic in nature obtained from petroleum. It is refined to meet the following specifications:

(1) It meets the test requirements of U.S.P. XVII for readily carbonizable substances (page 399).

(2) It meets the test requirements of U.S.P. XVII for sulfur compounds (page 400).

(3) It meets the specifications prescribed in the Journal of the Association of Official Analytical Chemists, Volume 45, page 66 (1962) [1] after correction of the ultraviolet absorbance for any absorbance due to added antioxidants.

(b) White mineral oil may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the act, in an amount not greater than that required to produce its intended effect.

(c) White mineral oil is used or intended for use as follows:

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[1] "Collaborative Study of the Determination of Soluble Solids in Tomato Products by Refractive Index Expressed as Percent Sucrose" by Frank C. Lamb, National Canners Association, 1950 Sixth Street, Berkeley, CA 94710, "Journal of the Association of Official Analytical Chemists," vol. 52, No. 5 (1969), pp. 1050–54. Adopted as official, first action at the 1969 AOAC meeting.

Use	Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with white mineral oil)
1. As a release agent, binder, and lubricant in or on capsules and tablets containing concentrates of flavoring, spices, condiments, and nutrients intended for addition to food, excluding confectionery.	Not to exceed 0.6% of the capsule or tablet.
2. As a release agent, binder, and lubricant in or on capsules and tablets containing food for special dietary use.	Not to exceed 0.6% of the capsule or tablet.
3. As a float on fermentation fluids in the manufacture of vinegar and wine to prevent or retard access of air, evaporation, and wild yeast contamination during fermentation.	In an amount not to exceed good manufacturing practice.
4. As a defoamer in food	In accordance with § 173.340 of this chapter.
5. In bakery products, as a release agent and lubricant	Not to exceed 0.15% of bakery products.
6. In dehydrated fruits and vegetables, as a release agent.	Not to exceed 0.02% of dehydrated fruits and vegetables.
7. In egg white solids, as a release agent	Not to exceed 0.1% of egg white solids.
8. On raw fruits and vegetables, as a protective coating	In an amount not to exceed good manufacturing practice.
9. In frozen meat, as a component of hot-melt coating	Not to exceed 0.095% of meat.
10. As a protective float on brine used in the curing of pickles.	In an amount not to exceed good manufacturing practice.
11. In molding starch used in the manufacture of confectionery.	Not to exceed 0.3 percent in the molding starch.
12. As a release agent, binder, and lubricant in the manufacture of yeast.	Not to exceed 0.15 percent of yeast.
13. As an antidusting agent in sorbic acid for food use	Not to exceed 0.25 percent in the sorbic acid.
14. As release agent and as sealing and polishing agent in the manufacture of confectionery.	Not to exceed 0.2 percent of confectionery.

§ 172.880 Petrolatum.

Petrolatum may be safely used in food, subject to the provisions of this section.

(a) Petrolatum complies with the specifications set forth in the U.S. Pharmacopeia XVII for white petrolatum or in The National Formulary XII for petrolatum.

(b) Petrolatum meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in § 172.886(b):

Ultraviolet absorbance per centimeter path length:

Millimicrons:	Maximum
280–289	0.35
290–299	.20
300–359	.14
360–400	.04

(c) Petrolatum is used or intended for use as follows:

Use	Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with petrolatum)
In bakery products; as release agent and lubricant.	With white mineral oil, not to exceed 0.15 percent of bakery product.
In confectionery; as release agent and as sealing and polishing agent.	Not to exceed 0.2 percent of confectionery.
In dehydrated fruits and vegetables; as release agent.	Not to exceed 0.02 percent of dehydrated fruits and vegetables.
In egg white solids; as release agent	Not to exceed 0.1 percent of egg white solids.
On raw fruits and vegetables; as protective coating.	In an amount not to exceed good manufacturing practice.
In beet sugar and yeast; as defoaming agent.	As prescribed in § 173.340 of this chapter.

(d) Petrolatum may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the act, in an amount not greater than that required to produce its intended effect.

§ 172.882 Synthetic isoparaffinic petroleum hydrocarbons.

Synthetic isoparaffinic petroleum hydrocarbons may be safely used in food, in accordance with the following conditions:

(a) They are produced by synthesis from petroleum gases and consist of a mixture of liquid hydrocarbons meeting the following specifications:

Boiling point 200°–500° F, as determined by A.S.T.M. Method D–86.

Ultraviolet absorbance:
260–319 millimicrons—1.5 maximum.
320–329 millimicrons—0.08 maximum.
330–350 millimicrons—0.05 maximum.

Nonvolatile residue: 0.002 gram per 100 milliliters maximum.

Synthetic isoparaffinic petroleum hydrocarbons containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. The ultraviolet absorbance shall be determined by the procedure described for application to mineral oil under "Specifications" on page 66 of the Journal of the Association of Official Analytical Chemists, Vol. 45 (February 1962), disregarding the last sentence of that procedure. For hydrocarbons boiling below 250° F, the nonvolatile residue shall be determined by A.S.T.M. procedure D–1353; for those boiling above 250° F, A.S.T.M. procedure D–381 shall be used.

(b) Isoparaffinic petroleum hydrocarbons may contain antioxidants authorized for use in food in an amount not to exceed that reasonably required to accomplish the intended technical effect nor to exceed any prescribed limitations.

(c) Synthetic isoparaffinic petroleum hydrocarbons are used or intended for use as follows:

Uses	Limitations
1. In the froth-flotation cleaning of vegetables.	In an amount not to exceed good manufacturing practice.
2. As a component of insecticide formulations for use on processed foods.	Do.
3. As a component of coatings on fruits and vegetables.	Do.
4. As a coating on shell eggs.	Do.
5. As a float on fermentation fluids in the manufacture of vinegar and wine and on brine used in curing pickles, to prevent or retard access of air, evaporation, and contamination with wild organisms during fermentation.	Do.

§ 172.884 Odorless light petroleum hydrocarbons.

Odorless light petroleum hydrocarbons may be safely used in food, in accordance with the following prescribed conditions:

(a) The additive is a mixture of liquid hydrocarbons derived from petroleum or synthesized from petroleum gases. The additive is chiefly paraffinic, isoparaffinic, or naphthenic in nature.

(b) The additive meets the following specifications:

(1) Odor is faint and not kerosenic.

(2) Initial boiling point is 300° F minimum.

(3) Final boiling point is 650° F maximum.

(4) Ultraviolet absorbance limits determined by method specified in § 178.-

3620(b)(1)(ii) of this chapter, as follows:

Wavelength mμ:	Maximum absorbance per centimeter optical pathlength
280–289	4.0
290–299	3.3
300–329	2.3
330–360	.8

(c) The additive is used as follows:

Use	Limitations
As a coating on shell eggs	In an amount not to exceed good manufacturing practice.
As a defoamer in processing beet sugar and yeast.	Complying with § 173.340 of this chapter.
As a float on fermentation fluids in the manufacture of vinegar and wine to prevent or retard access of air, evaporation, and wild yeast contamination during fermentation.	In an amount not to exceed good manufacturing practice.
In the froth-flotation cleaning of vegetables.	Do.
As a component of insecticide formulations used in compliance with regulations issued in Parts 170 through 189 of this chapter.	Do.

§ 172.886 Petroleum wax.

Petroleum wax may be safely used in or on food, in accordance with the following conditions:

(a) Petroleum wax is a mixture of solid hydrocarbons, paraffinic in nature, derived from petroleum, and refined to meet the specifications prescribed by this section.

(b) Petroleum wax meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in this paragraph.

	Ultraviolet absorbance per centimeter path length
280–289 millimicrons	0.15 maximum
290–299 millimicrons	0.12 maximum
300–359 millimicrons	0.06 maximum
360–400 millimicrons	0.02 maximum

ANALYTICAL SPECIFICATION FOR PETROLEUM WAX

General Instructions

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of wax samples is handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

Apparatus

Separatory funnels. 250-milliliter, 500-milliliter, 1,000-milliliter, and preferably 2,000-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Reservoir. 500-milliliter capacity, equipped with a 24/40 standard taper male fitting at the bottom and a suitable ball-joint at the top for connecting to the nitrogen supply. The male fitting should be equipped with glass hooks.

Chromatographic tube. 180 millimeters in length, inside diameter to be 15.7 millimeters ±0.1 millimeter, equipped with a coarse, fritted-glass disc, a tetrafluoroethylene polymer stopcock, and a female 24/40 standard tapered fitting at the opposite end. (Over-all length of the column with the female joint is 235 millimeters.) The female fitting should be equipped with glass hooks.

Disc. Tetrafluoroethylene polymer 2-inch diameter disc approximately 3/16-inch thick with a hole bored in the center to closely fit the stem of the chromatographic tube.

Heating jacket. Conical, for 500-milliliter separatory funnel. (Used with variable transformer heat control.)

Suction flask. 250-milliliter or 500-milliliter filter flask.

Condenser. 24/40 joints, fitted with a drying tube, length optional.

Evaporation flask (optional). 250-milliliter or 500-milliliter capacity all-glass flask equipped with standard taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of contained liquid to be evaporated.

Vacuum distillation assembly. All glass (for purification of dimethyl sulfoxide); 2-liter distillation flask with heating mantle; Vigreaux vacuum-jacketed condenser (or equivalent) about 45 centimeters in length and distilling head with separable cold finger condenser. Use of tetrafluoroethylene polymer sleeves on the glass joints will prevent freezing. Do not use grease on stopcocks or joints.

Spectrophotometric cells. Fused quartz cells, optical path length in the range of 5.000 centimeters ±0.005 centimeter; also for checking spectrophotometer performance only, optical path length in the range 1.000 centimeter ±0.005 centimeter. With distilled water in the cells, determine any absorbance differences.

Spectrophotometer. Spectral range 250 millimicrons–400 millimicrons with spectral slit width of 2 millimicrons or less; under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Absorbance accuracy,[1] ±0.05 at 0.4 absorbance.

Wavelength repeatability, ±0.2 millimicron.

Wavelength accuracy, ±1.0 millimicron.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

REAGENTS AND MATERIALS

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane, benzene, acetone, and methyl alcohol designated in the list following this paragraph shall pass the following test:

To the specified quantity of solvent in a 250-milliliter Erlenmeyer flask, add 1 milliliter of purified *n*-hexadecane and evaporate on the steam bath under a stream of nitrogen (a loose aluminum foil jacket around the flask will speed evaporation). Discontinue evaporation when not over 1 milliliter of residue remains. (To the residue from benzene add a 10-milliliter portion of purified isooctane, reevaporate, and repeat once to insure complete removal of benzene.)

Alternatively, the evaporation time can be reduced by using the optional evaporation flask. In this case the solvent and *n*-hexadecane are placed in the flask on the steam bath, the tube assembly is inserted, and a stream of nitrogen is fed through the inlet tube while the outlet tube is connected to a solvent trap and vacuum line in such a way as to prevent any flow-back of condensate into the flask.

Dissolve the 1 milliliter of hexadecane residue in isooctane and make to 25 milliliters volume. Determine the absorbance in the 5-centimeter path length cells compared to isooctane as reference. The absorbance of the solution of the solvent residue (except for methyl alcohol) shall not exceed 0.01 per centimeter path length between 280 and 400 mμ. For methyl alcohol this absorbance value shall be 0.00.

Isooctane (2,2,4-trimethylpentane). Use 180 milliliters for the test described in the preceding paragraph. Purify, if necessary, by passage through a column of activated silica gel (Grade 12, Davison Chemical Company, Baltimore, Maryland, or equivalent) about 90 centimeters in length and 5 centimeters to 8 centimeters in diameter.

Benzene, A.C.S. reagent grade. Use 150 milliliters for the test. Purify, if necessary, by distillation or otherwise.

Acetone, A.C.S. reagent grade. Use 200 milliliters for the test. Purify, if necessary, by distillation.

Eluting mixtures:

1. *10 percent benzene in isooctane.* Pipet 50 milliliters of benzene into a 500-milliliter glass-stoppered volumetric flask and adjust to volume with isooctane, with mixing.

2. *20 percent benzene in isooctane.* Pipet 50 milliliters of benzene into a 250-milliliter glass-stoppered volumetric flask, and adjust to volume with isooctane, with mixing.

3. *Acetone-benzene-water mixture.* Add 20 milliliters of water to 380 milliliters of acetone and 200 milliliters of benzene, and mix.

n-Hexadecane, 99 percent olefin-free. Dilute 1.0 milliliter of *n*-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 5-centimeter cell compared to isooctane as reference point between 280 mμ–400 mμ. The absorbance per centimeter path length shall not exceed 0.00 in this range. Purify, if necessary, by percolation through activated silica gel or by distillation.

Methyl alcohol, A.C.S. reagent grade. Use 10.0 milliliters of methyl alcohol. Purify, if necessary, by distillation.

Dimethyl sulfoxide. Pure grade, clear, water-white, m.p. 18° minimum. Dilute 120 milliliters of dimethyl sulfoxide with 240 milliliters of distilled water in a 500-milliliter separatory funnel, mix and allow to cool for 5–10 minutes. Add 40 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second 500-milliliter separatory funnel and repeat the extraction with 40 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 40-milliliter extractives three times with 50-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see *Sodium sulfate under* "Reagents and Materials" for preparation of filter), into a 250-milliliter Erlenmeyer flask, or optionally into the evaporating flask. Wash the first separatory funnel with the second 40-milliliter isooctane extractive, and pass through the sodium sulfate into the flask. Then wash

[1] As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, 1949. The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons.

the second and first separatory funnels successively with a 10-milliliter portion of isooctane, and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of *n*-hexadecane and evaporate the isooctane on the steam bath under nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10-milliliter portion of isooctane and reevaporate to 1 milliliter of hexadecane. Again, add 10 milliliters of isooctane to the residue and evaporate to 1 milliliter of hexadecane to insure complete removal of all volatile materials. Dissolve the 1 milliliter of hexadecane in isooctane and make to 25-milliliter volume. Determine the absorbance in 5-centimeter path length cells compared to isooctane as reference. The absorbance of the solution should not exceed 0.02 per centimeter path length in the 280 mμ–400 mμ range. (NOTE.—Difficulty in meeting this absorbance specification may be due to organic impurities in the distilled water. Repetition of the test omitting the dimethyl sulfoxide will disclose their presence. If necessary to meet the specification, purify the water by redistillation, passage through an ion-exchange resin, or otherwise.)

Purify, if necessary, by the following procedure: To 1,500 milliliters of dimethyl sulfoxide in a 2-liter glass-stoppered flask, add 6.0 milliliters of phosphoric acid and 50 grams of Norit A (decolorizing carbon, alkaline) or equivalent. Stopper the flask, and with the use of a magnetic stirrer (tetrafluoroethylene polymer coated bar) stir the solvent for 15 minutes. Filter the dimethyl sulfoxide through four thicknesses of fluted paper (18.5 centimeters, Schleicher & Schuell, No. 597, or equivalent). If the initial filtrate contains carbon fines, refilter through the same filter until a clear filtrate is obtained. Protect the sulfoxide from air and moisture during this operation by covering the solvent in the funnel and collection flask with a layer of isooctane. Transfer the filtrate to a 2-liter separatory funnel and draw off the dimethyl sulfoxide into the 2-liter distillation flask of the vacuum distillation assembly and distill at approximately 3-millimeter Hg pressure or less. Discard the first 200-milliliter fraction of the distillate and replace the distillate collection flask with a clean one. Continue the distillation until approximately 1 liter of the sulfoxide has been collected.

At completion of the distillation, the reagent should be stored in glass-stoppered bottles since it is very hygroscopic and will react with some metal containers in the presence of air.

Phosphoric acid. 85 percent A.C.S. reagent grade.

Sodium borohydride. 98 percent.

Magnesium oxide (Sea Sorb 43, Food Machinery Company, Westvaco Division, distributed by chemical supply firms, or equivalent). Place 100 grams of the magnesium oxide in a large beaker, add 700 milliliters of distilled water to make a thin slurry, and heat on a steam bath for 30 minutes with intermittent stirring. Stir well initially to insure that all the absorbent is completely wetted. Using a Buchner funnel and a filter paper (Schleicher & Schuell No. 597, or equivalent) of suitable diameter, filter with suction. Continue suction until water no longer drips from the funnel. Transfer the absorbent to a glass trough lined with aluminum foil (free from rolling oil). Break up the magnesia with a clean spatula and spread out the absorbent on the aluminum foil in a layer about 1 centimeter to 2 centimeters thick. Dry for 24 hours at 160° C ± 1° C. Pulverize the magnesia with mortar and pestle. Sieve the pulverized absorbent between 60–180 mesh. Use the magnesia retained on the 180-mesh sieve.

Celite 545. Johns-Manville Company, diatomaceous earth, or equivalent.

Magnesium oxide-Celite 545 mixture (2+1) by weight. Place the magnesium oxide (60–180 mesh) and the Celite 545 in 2 to 1 proportions, respectively, by weight in a glass-stoppered flask large enough for adequate mixing. Shake vigorously for 10 minutes. Transfer the mixture to a glass trough lined with aluminum foil (free from rolling oil) and spread it out on a layer about 1 centimeter to 2 centimeters thick. Reheat the mixture at 160° C ± 1° C for 2 hours, and store in a tightly closed flask.

Sodium sulfate, anhydrous, A.C.S. reagent grade, preferably in granular form. For each bottle of sodium sulfate reagent used, establish as follows the necessary sodium sulfate prewash to provide such filters required in the method: Place approximately 35 grams of anhydrous sodium sulfate in a 30-milliliter coarse, fritted-glass funnel or in a 65-millimeter filter funnel with glass wool plug; wash with successive 15-milliliter portions of the indicated solvent until a 15-milliliter portion of the wash shows 0.00 absorbance per centimeter path length between 280 mμ and 400 mμ when tested as prescribed under "Organic solvents." Usually three portions of wash solvent are sufficient.

Before proceeding with analysis of a sample, determine the absorbance in a 5-centimeter path cell between 250 mμ and 400 mμ for the reagent blank by carrying out the procedure, without a wax sample, at room temperature, recording the spectra after the extraction stage and after the complete procedure as prescribed. The absorbance per centimeter path length following the extraction stage should not exceed 0.040 in the wavelength range from 280 mμ to 400 mμ; the absorbance per centimeter path length following the complete procedure should not exceed 0.070 in the wavelength range from 280 mμ to 299 mμ, inclusive, nor 0.045 in the wavelength range from 300 mμ to 400 mμ. If in either spectrum the characteristic benzene peaks in the 250 mμ–260 mμ region are present, remove the benzene by the procedure under "Organic solvents" and record absorbance again.

Place 300 milliliters of dimethyl sulfoxide in a 1-liter separatory funnel and add 75 milliliters of phosphoric acid. Mix the contents of the funnel and allow to stand for 10 minutes. (The reaction between the sulfoxide and the acid is exothermic. Release pressure after mixing, then keep funnel stoppered.) Add 150 milliliters of isooctane and shake to preequilibrate the solvents. Draw off the individual layers and store in glass-stoppered flasks.

Place a representative 1-kilogram sample of wax, or if this amount is not available, the entire sample, in a beaker of a capacity about three times the volume of the sample and heat with occasional stirring on a steam bath until the wax is completely melted and homogeneous. Weigh four 25-gram ±0.2 gram portions of the melted wax in separate 100-milliliter beakers. Reserve three of the portions for later replicate analyses as necessary. Pour one weighed portion immediately after remelting (on the steam bath) into a 500-milliliter separatory funnel containing 100 milliliters of the preequilibrated sulfoxide-phosphoric acid mixture that has been heated in the heating jacket at a temperature just high enough to keep the wax melted. (NOTE: In preheating the sulfoxide-acid mixture, remove the stopper of the separatory funnel at intervals to release the pressure.)

Promptly complete the transfer of the sample to the funnel in the jacket with portions of the preequilibrated isooctane, warming the beaker, if necessary, and using a total volume of just 50 milliliters of the solvent. If the wax comes out of solution during these operations, let the stoppered funnel remain in the jacket until the wax redissolves. (Remove stopper from the funnel at intervals to release pressure.) When the wax is in solution, remove the funnel from the jacket and shake it vigorously for 2 minutes. Set up three 250-milliliter separatory funnels with each containing 30 milliliters of preequilibrated isooctane. After separation of the liquid phases, allow to cool until the main portion of the wax-isooctane solution begins to show a precipitate. Gently swirl the funnel when precipitation first occurs on the inside surface of the funnel to accelerate this process. Carefully draw off the lower layer, filter it slowly through a thin layer of glass wool fitted loosely in a filter funnel into the first 250-milliliter separatory funnel, and wash in tandem with the 30-milliliter portions of isooctane contained in the 250-milliliter separatory funnels. Shaking time for each wash is 1 minute. Repeat the extraction operation with two additional portions of the sulfoxide-acid mixture, replacing the funnel in the jacket after each extraction to keep the wax in solution and washing each extractive in tandem through the same three portions of isooctane.

Collect the successive extractives (300 milliliters total) in a separatory funnel (preferably 2-liter), containing 480 milliliters of distilled water, mix, and allow to cool for a few minutes after the last extractive has been added. Add 80 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second separatory funnel (preferably 2-liter) and repeat the extraction with 80 milliliters of isooctane Draw off and discard the aqueous layer. Wash each of the 80-milliliter extractives three times with 100-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see *Sodium Sulfate* under "Reagents and Materials" for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the first separatory funnel with the second 80-milliliter isooctane extractive and pass through the sodium sulfate. Then wash the second and first separatory funnels successively with a 20-milliliter portion of isooctane and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of *n*-hexadecane and evaporate the isooctane on the steam bath under nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10-milliliter portion of isooctane, reevaporate to 1 milliliter of hexadecane, and repeat this operation once.

Quantitatively transfer the residue with isooctane to a 25-milliliter volumetric flask, make to volume, and mix. Determine the absorbance of the solution in the 5-centimeter path length cells compared to isooctane as reference between 280 mμ–400 mμ (take care to lose none of the solution in filling the sample cell). Correct the absorbance values for any absorbance derived from reagents as determined by carrying out the procedure without a wax sample. If the corrected absorbance does not exceed the limits prescribed in this paragraph (b), the wax meets the ultraviolet absorbance specifications. If the corrected absorbance per centimeter path length exceeds the limits prescribed in this paragraph (b), proceed as follows:

Quantitatively transfer the isooctane solution to a 125-milliliter flask equipped with 24/40 joint and evaporate the isooctane on the steam bath under a stream of nitrogen to a volume of 1 milliliter of hexadecane. Add 10 milliliters of methyl alcohol and approximately 0.3 gram of sodium borohydride. (Minimize exposure of the borohydride to the atmosphere. A measuring dipper may be used.) Immediately fit a water-cooled condenser equipped with a 24/40 joint and with

a drying tube into the flask, mix until the borohydride is dissolved, and allow to stand for 30 minutes at room temperature, with intermittent swirling. At the end of this period, disconnect the flask and evaporate the methyl alcohol on the steam bath under nitrogen until the sodium borohydride begins to come out of the solution. Then add 10 milliliters of isooctane and evaporate to a volume of about 2–3 milliliters. Again, add 10 milliliters of isooctane and concentrate to a volume of approximately 5 milliliters. Swirl the flask repeatedly to assure adequate washing of the sodium borohydride residues.

Fit the tetrafluoroethylene polymer disc on the upper part of the stem of the chromatographic tube, then place the tube with the disc on the suction flask and apply the vacuum (approximately 135 millimeters Hg pressure). Weight out 14 grams of the 2:1 magnesium oxide–Celite 545 mixture and pour the adsorbent mixture into the chromatographic tube in approximately 3-centimeter layers. After the addition of each layer, level off the top of the adsorbent with a flat glass rod or metal plunger by pressing down firmly until the adsorbent is well packed. Loosen the topmost few millimeters of each adsorbent layer with the end of a metal rod before the addition of the next layer. Continue packing in this manner until all the 14 grams of the adsorbent is added to the tube. Level off the top of the absorbent by pressing down firmly with a flat glass rod or metal plunger to make the depth of the adsorbent bed approximately 12.5 centimeters in depth. Turn off the vacuum and remove the suction flask. Fit the 500-milliliter reservoir onto the top of the chromatographic column and prewet the column by passing 100 milliliters of isooctane through the column. Adjust the nitrogen pressure so that the rate of descent of the isooctane coming off of the column is between 2–3 milliliters per minute. Discontinue pressure just before the last of the isooctane reaches the level of the adsorbent. (CAUTION: Do not allow the liquid level to recede below the adsorbent level at any time.) Remove the reservoir and decant the 5-milliliter isooctane concentrate solution onto the column and with slight pressure again allow the liquid level to recede to barely above the adsorbent level. Rapidly complete the transfer similarly with two 5-milliliter portions of isooctane, swirling the flask repeatedly each time to assure adequate washing of the residue. Just before the final 5-milliliter wash reaches the top of the adsorbent, add 100 milliliters of isooctane to the reservoir and continue the percolation at the 2–3 milliliter per minute rate. Just before the last of the isooctane reaches the adsorbent level, add 100 milliliters of 10 percent benzene in isooctane to the reservoir and continue the percolation at the aforementioned rate. Just before the solvent mixture reaches adsorbent level, add 25 milliliters of 20 percent benzene in isooctane to the reservoir and continue the percolation at 2–3 milliliters per minute until all this solvent mixture has been removed from the column. Discard all the elution solvents collected up to this point. Add 300 milliliters of the acetone-benzene-water mixture to the reservoir and percolate through the column to elute the polynuclear compounds. Collect the eluate in a clean 1-liter separatory funnel. Allow the column to drain until most of the solvent mixture is removed. Wash the eluate three times with 300-milliliter portions of distilled water, shaking well for each wash. (The addition of small amounts of sodium chloride facilitates separation.) Discard the aqueous layer after each wash. After the final separation, filter the residual benzene through anhydrous sodium sulfate prewashed with benzene (see *Sodium sulfate* under "Reagents and Materials" for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the separatory funnel with two additional 20-milliliter portions of benzene which are also filtered through the sodium sulfate. Add 1 milliliter of *n*-hexadecane and completely remove the benzene by evaporation under nitrogen, using the special procedure to eliminate benzene as previously described under "Organic Solvents." Quantitatively transfer the residue with isooctane to a 25-milliliter volumetric flask and adjust to volume. Determine the absorbance of the solution in the 5-centimeter path length cells compared to isooctane as reference between 250 $m\mu$–400 $m\mu$. Correct for any absorbance derived from the reagents as determined by carrying out the procedure without a wax sample. If either spectrum shows the characteristic benzene peaks in the 250 $m\mu$–260 $m\mu$ region, evaporate the solution to remove benzene by the procedure under "Organic Solvents." Dissolve the residue, transfer quantitatively, and adjust to volume in isooctane in a 25-milliliter volumetric flask. Record the absorbance again. If the corrected absorbance does not exceed the limits prescribed in this paragraph (b), the wax meets the ultraviolet absorbance specifications.

(c) Petroleum wax may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the act, in an amount not greater than that required to produce its intended effect.

(d) Petroleum wax is used or intended for use as follows:

Use	*Limitations*
In chewing gum base, as a masticatory substance.	In an amount not to exceed good manufacturing practice.
On cheese and raw fruits and vegetables as a protective coating.	Do.
As a defoamer in food.	In accordance with § 173.340 of this chapter.

§ 172.888 Synthetic petroleum wax.

Synthetic petroleum wax may be safely used in or on foods in accordance with the following conditions:

(a) Synthetic petroleum wax is a mixture of solid hydrocarbons, paraffinic in nature, prepared by catalytic polymerization of ethylene, and refined to meet the specifications prescribed by this section.

(b) Synthetic petroleum wax meets the ultraviolet absorbance limits of § 172.886(b) when subjected to the analytical procedure described therein.

(c) Synthetic petroleum wax has a number average molecular weight of not less than 500 nor greater than 1,200 as determined by vapor pressure osmometry.

(d) Synthetic petroleum wax may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the Act, in an amount not greater than that required to produce its intended effect.

(e) Synthetic petroleum wax is used or intended for use as follows:

Use	*Limitations*
In chewing gum base, as a masticatory substance.	In accordance with § 172.615 in an amount not to exceed good manufacturing practice.
On cheese and raw fruits and vegetables as a protective coating.	In an amount not to exceed good manufacturing practice.
As a defoamer in food.	In accordance with § 173.340 of this chapter.

§ 172.890 Rice bran wax.

Rice bran wax may be safely used in food in accordance with the following conditions:

(a) It is the refined wax obtained from rice bran and meets the following specifications:

Melting point 75° C to 80° C.
Free fatty acids, maximum 10 percent.
Iodine number, maximum 20.
Saponification number 75 to 120.

(b) It is used or intended for use as follows:

Food	Limitation in food	Use
Candy	50 p.p.m.	Coating.
Fresh fruits and fresh vegetables.	do.	Do.
Chewing gum	2½ pct	Plasticizing material.

§ 172.892 Food starch-modified.

Food starch-modified as described in this section may be safely used in food. The quantity of any substance employed to effect such modification shall not exceed the amount reasonably required to accomplish the intended physical or technical effect, nor exceed any limitation prescribed. To insure safe use of the food starch-modified, the label of the food additive container shall bear the name of the additive "food starch-modified" in addition to other information required by the act. Food starch may be modified by treatment prescribed as follows:

(a) Food starch may be acid-modified by treatment with hydrochloric acid or sulfuric acid or both.

(b) Food starch may be bleached by treatment with one or more of the following:

	Limitations
Active oxygen obtained from hydrogen peroxide and/or peracetic acid, not to exceed 0.45 percent of active oxygen.	
Ammonium persulfate, not to exceed 0.075 percent and sulfur dioxide, not to exceed 0.05 percent.	
Chlorine, as sodium hypochlorite, not to exceed 0.0082 pound of chlorine per pound of dry starch.	
Potassium permanganate, not to exceed 0.2 percent.	Residual manganese (calculated as Mn), not to exceed 50 parts per million in food starch-modified.
Sodium chlorite, not to exceed 0.5 percent.	

(c) Food starch may be oxidized by treatment with chlorine, as sodium hypochlorite, not to exceed 0.055 pound of chlorine per pound of dry starch.

(d) Food starch may be esterified by treatment with one of the following:

	Limitations
Acetic anhydride	Acetyl groups in food starch-modified not to exceed 2.5 percent.
Adipic anhydride, not to exceed 0.12 percent, and acetic anhydride.	Do.
Monosodium orthophosphate.	Residual phosphate in food starch-modified not to exceed 0.4 percent calculated as phosphorus.
1-Octenyl succinic anhydride, not to exceed 3 percent.	----------
1-Octenyl succinic anhydride, not to exceed 2 percent, and aluminum sulfate, not to exceed 2 percent.	----------
Phosphorus oxychloride, not to exceed 0.1 percent.	----------
Phosphorus oxychloride, not to exceed 0.1 percent, followed by either acetic anhydride, not to exceed 8 percent, or vinyl acetate, not to exceed 7.5 percent.	Acetyl groups in food starch-modified not to exceed 2.5 percent.
Sodium trimetaphosphate.	Residual phosphate in food starch-modified not to exceed 0.04 percent, calculated as phosphorus.
Sodium tripolyphosphate and sodium trimetaphosphate.	Residual phosphate in food starch-modified not to exceed 0.4 percent calculated as phosphorus.
Succinic anhydride, not to exceed 4 percent.	----------
Vinyl acetate.	Acetyl groups in food starch-modified not to exceed 2.5 percent.

(e) Food starch may be etherified by treatment with one of the following:

	Limitations
Acrolein, not to exceed 0.6 percent.	----------
Epichlorohydrin, not to exceed 0.3 percent.	----------
Epichlorohydrin, not to exceed 0.1 percent, combined with propylene oxide, not to exceed 10 percent.	Residual propylene chlorohydrin not more than 5 parts per million in food starch-modified.
Epichlorohydrin, not to exceed 0.1 percent, followed by propylene oxide, not to exceed 25 percent.	Do.
Propylene oxide, not to exceed 25 percent.	Do.

(f) Food starch may be esterified and etherified by treatment with one of the following:

	Limitations
Acrolein, not to exceed 0.6 percent and vinyl acetate, not to exceed 7.5 percent.	Acetyl groups in food starch-modified not to exceed 2.5 percent.
Epichlorohydrin, not to exceed 0.3 percent, and acetic anhydride.	Acetyl groups in food starch-modified not to exceed 2.5 percent.
Epichlorohydrin, not to exceed 0.3 percent, and succinic anhydride, not to exceed 4 percent.	----------
Phosphorus oxychloride, not to exceed 0.1 percent, and propylene oxide, not to exceed 10 percent.	Residual propylene chlorohydrin not more than 5 parts per million in food starch-modified.

(g) Food starch may be modified by treatment with one of the following:

	Limitations
Chlorine, as sodium hypochlorite, not to exceed 0.055 pound of chlorine per pound of dry starch; 0.45 percent of active oxygen obtained from hydrogen peroxide; and propylene oxide, not to exceed 25 percent.	Residual propylene chlorohydrin not more than 5 parts per million in food starch-modified.
Sodium hydroxide, not to exceed 1 percent.	----------

(h) Food starch may be modified by a combination of the treatments prescribed by paragraphs (a) and/or (b) of this section and any one of the treatments prescribed by paragraph (c), (d), (e), (f), or (g) of this section, subject to any limitations prescribed by the paragraphs named.

§ 172.894 Modified cottonseed products intended for human consumption.

The food additive modified cottonseed products may be used for human consumption in accordance with the following prescribed conditions:

(a) The additive is derived from:

(1) Decorticated, partially defatted, cooked, ground cottonseed kernels; or

(2) Decorticated, ground cottonseed kernels, in a process that utilizes *n*-hexane as an extracting solvent in such a way that no more than 60 parts per million of *n*-hexane residues and less than 1 percent fat by weight remain in the finished product; or

(3) Glandless cottonseed kernels roasted to attain a temperature of not less than 250° F in the kernel for not less than 5 minutes for use as a snack food, or in baked goods, or in soft candy; or

(4) Raw glandless cottonseed kernels may be used in hard candy where the kernel temperature during cooking will exceed 250° F for not less than 5 minutes.

(b) The additive is prepared to meet the following specifications:

(1) Free gossypol content not to exceed 450 parts per million.

(2) It contains no added arsenic compound and therefore may not exceed a maximum natural background level of 0.2 part per million total arsenic, calculated as As.

(c) To assure safe use of the additive, the label of the food additive container shall bear, in addition to other information required by the act, the name of the additive as follows:

(1) The additive identified in paragraph (a)(1) of this section as "partially defatted, cooked cottonseed flour".

(2) The additive identified in paragraph (a)(2) of this section as "defatted cottonseed floor".

(3) The additive identified in paragraph (a)(3) of this section as "roasted glandles cottonseed kernels".

(4) The additive identified in paragraph (a)(4) of this section as "raw glandless cottonseed kernels for use in cooked hard candy".

(d) The Food and Drug Administration and the Environmental Protection Agency have determined that glandless cottonseed kernels permitted for use by this section are a distinct commodity from glanded cottonseed.

§ 172.896 Dried yeasts.

Dried yeast (*Saccharomyces cerevisiae* and *Saccharomyces fragilis*) and dried torula yeast (*Candida utilis*) may be safely used in food provided the total folic acid content of the yeast does not exceed 0.04 milligram per gram of yeast (approximately 0.008 milligram of pteroyglutamic acid per gram of yeast).

§ 172.898 Bakers yeast glycan.

Bakers yeast glycan may be safely used in food in accordance with the following conditions:

(a) Bakers yeast glycan is the comminuted, washed, pasteurized, and dried cell walls of the yeast, *Saccharomyces cerevisiae*. It is composed principally of long chain carbohydrates, not less than 85 percent on a dry solids basis. The carbohydrate is composed of glycan and mannan units in approximately a 2:1 ratio.

(b) The additive meets the following specifications on a dry weight basis: Less than 0.4 part per million (ppm) arsenic, 0.13 ppm cadmium, 0.2 ppm lead, 0.05 ppm mercury, 0.09 ppm selenium, and 10 ppm zinc.

(c) The viable microbial content of the finished ingredient is:

(1) Less than 10,000 organisms/gram by aerobic plate count.

(2) Less than 10 yeasts and molds/gram.

(3) Negative for *Salmonella*, *E. coli*, coagulase positive *Staphylococci*, *Clostridium perfringens*, *Clostridium botulinum*, or any other recognized microbial pathogen or any harmful microbial toxin.

(d) The additive is used or intended for use only in salad dressings as an emulsifier and emulsifier salt as defined in § 170.3(o)(8) of this chapter, stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter

at a maximum concentration of 5 percent.

(e) The label and labeling of the ingredient shall bear adequate directions to assure that use of the ingredient complies with this regulation.

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

Subpart A—Polymer Substances for Food Treatment

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173.350 Combustion product gas.
173.355 Dichlorodifluoromethane.
173.360 Octafluorocyclobutane.
173.385 Sodium methyl sulfate.

AUTHORITY: Secs. 409, 701, 52 Stat. 1055–1056, 72 Stat. 1785–1786 as amended (21 U.S.C. 348, 371), unless otherwise noted.

Subpart A—Polymer Substances for Food Treatment

§ 173.5 Acrylate-acrylamide resins.

Acrylate-acrylamide resins may be safely used in food under the following prescribed conditions:

(a) The additive consists of one of the following:

(1) Acrylamide-acrylic acid resin (hydrolyzed polyacrylamide) is produced by the polymerization of acrylamide with partial hydrolysis, or by copolymerization of acrylamide and acrylic acid, with the greater part of the polymer being composed of acrylamide units.

(2) Sodium polyacrylate-acrylamide resin is produced by the polymerization and subsequent hydrolysis of acrylonitrile in a sodium silicate-sodium hydroxide aqueous solution, with the greater part of the polymer being composed of acrylate units.

(b) The additive contains not more than 0.05 percent of residual monomer calculated as acrylamide.

(c) The additive is used or intended for use as follows:

(1) The additive identified in paragraph (a)(1) of this section is used as a flocculent in the clarification of beet sugar juice and liquor or cane sugar juice and liquor in an amount not to exceed 5 parts per million by weight of the juice or 10 parts per million by weight of the liquor.

(2) The additive identified in paragraph (a)(2) of this section is used to control organic and mineral scale in beet sugar juice and liquor or cane sugar juice and liquor in an amount not to exceed 2.5 parts per million by weight of the juice or liquor.

§ 173.10 Modified polyacrylamide resin.

Modified polyacrylamide resin may be safely used in food in accordance with the following prescribed conditions:

(a) The modified polyacrylamide resin is produced by the copolymerization of acrylamide with not more than 5-mole percent β-methacrylyloxyethyltrimethylammonium methyl sulfate.

(b) The modified polyacrylamide resin contains not more than 0.05 percent residual acrylamide.

(c) The modified polyacrylamide resin is used as a flocculent in the clarification of beet or cane sugar juice in an amount not exceeding 5 parts per million by weight of the juice.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear, in addition to the other information required by the act, adequate directions to assure use in compliance with paragraph (c) of this section.

§ 173.20 Ion-exchange membranes.

Ion-exchange membranes may be safely used in the processing of food under the following prescribed conditions:

(a) The ion-exchange membrane is prepared by subjecting a polyethylene base conforming to § 177.1520 of this chapter to polymerization with styrene until the polystyrene phase of the base is not less than 16 percent nor more than 30 percent by weight. The base is then modified by reaction with chloromethyl methyl ether, and by subsequent amination with trimethylamine, dimethylamine, diethylenetriamine, or dimethylethanolamine.

(b) The ion-exchange membrane is manufactured so as to comply with the following extraction limitations when subjected to the described procedure: Separate square-foot samples of membrane weighing approximately 14 grams each are cut into small pieces and refluxed for 4 hours in 150 cubic centimeters of the following solvents: Distilled water, 5 percent acetic acid, and 50 percent alcohol. Extraction from each sample will not exceed 0.4 percent by weight of sample.

(c) The ion-exchange membrane will be used in the production of grapefruit juice to adjust the ratio of citric acid to total solids of the grapefruit juice produced.

§ 173.25 Ion-exchange resins.

Ion-exchange resins may be safely used in the treatment of food under the following prescribed conditions:

(a) The ion-exchange resins are prepared in appropriate physical form, and consist of one or more of the following:

(1) Sulfonated copolymer of styrene and divinylbenzene.

(2) Sulfonated anthracite coal meeting the requirements of ASTM–D388–38, Class I, Group 2.

(3) Sulfite-modified, cross-linked phenol-formaldehyde, with modification resulting in sulfonic acid groups on side chains.

(4) Methacrylic acid-divinylbeneze copolymer.

(5) Cross-linked polystyrene, first chloromethylated then aminated with trimethylamine, dimethylamine, diethylenetriamine, or dimethylethanolamine.

(6) Diethylenetriamine, triethylenetetramine, or tetraethylenepentamine cross-linked with epichlorohydrin.

(7) Cross-linked phenol-formaldehyde activated with one or both of the following: Triethylene tetramine and tetraethylenepentamine.

(8) Reaction resin of formaldehyde, acetone, and tetraethylenepentamine.

(9) Completely hydrolyzed copolymers of methyl acrylate and divinylbenzene.

(10) Completely hydrolyzed terpolymers of methyl acrylate, divinylbenzene, and acrylonitrile.

(11) Sulfonated terpolymers of styrene, divinylbenzene, and acrylonitrile or methyl acrylate.

(12) Methyl acrylate-divinylbenzene copolymer containing not less than 2 percent by weight of divinylbenzene, aminolyzed with dimethylaminopropylamine.

(13) Methyl acrylate-divinylbenzene copolymer containing not less than 3.5 percent by weight of divinylbenzene, aminolyzed with dimethylaminopropylamine.

(14) Epichlorohydrin cross-linked with ammonia.

(15) Sulfonated tetrapolymer of styrene, divinylbenzene, acrylonitrile, and methyl acrylate derived from a mixture of monomers containing not more than a total of 2 percent by weight of acrylonitrile and methyl acrylate.

(16) Methyl acrylate-divinylbenzene-diethylene glycol divinyl ether terpolymer containing not less than 3.5 percent by weight of divinylbenzene and not more than 0.6 percent by weight of diethylene glycol divinyl ether, aminolyzed with dimethylaminopropylamine.

(17) Styrene - divinylbenzene cross-linked copolymer, first chloromethylated then aminated with dimethylamine and oxidized with hydrogen peroxide whereby the resin contains not more than 15 percent by weight of vinyl *N,N*-dimethylbenzylamine-*N*-oxide and not more than 6.5 percent by weight of nitrogen.

(b) Ion-exchange resins are used in the purification of foods, including potable water, to remove undesirable ions or to replace less desirable ions with one or more of the following: Bicarbonate, calcium, carbonate, chloride, hydrogen, hydroxyl, magnesium, potassium, sodium, and sulfate except that: The ion-exchange resin identified in paragraph (a)(12) of this section is used only in accordance with paragraph (b)(1) of this section, the ion-exchange resin identified in paragraph (a)(13) of this section is used only in accordance with paragraph (b)(2) of this section, the resin identified in paragraph (a)(16) of this section is used only in accordance with paragraph (b) (1) or (2) of this section, and the ion-exchange resin identified in paragraph (a)(17) of this section is used only in accordance with paragraph (b)(3) of this section.

(1) The ion-exchange resins identified in paragraph (a) (12) and (16) of this section are used to treat water for use in the manufacture of distilled alcoholic beverages, subject to the following conditions:

(i) The water is subjected to treatment through a mixed bed consisting of one of the resins identified in paragraph (a) (12) or (16) of this section and one of the strongly acidic cation-exchange resins in the hydrogen form identified in paragraph (a) (1), (2), and (11) of this section; or

(ii) The water is first subjected to one of the resins identified in paragraph (a) (12) or (16) of this section and is subsequently subjected to treatment through a bed of activated carbon or one of the strongly acidic cation-exchange resins in the hydrogen form identified in paragraph (a) (1), (2), and (11) of this section.

(iii) The temperature of the water passing through the resin beds identified in paragraph (b)(1) (i) and (ii) of this section is maintained at 30° C or less, and the flow rate of the water passing through the beds is not less than 2 gallons per cubic foot per minute.

(iv) The ion-exchange resins identified in paragraph (a) (12) or (16) of this section are exempted from the requirements of paragraph (c)(4) of this section, but the strongly acidic cation-exchange resins referred to in paragraph (b)(1) (i) and (ii) of this section used in the process meet the requirements of paragraph (c)(4) of this section, except for the exemption described in paragraph (d) of this section.

(2) The ion-exchange resins identified in paragraph (a) (13) and (16) of this section are used to treat water and aqueous food only of the types identified under categories I, II, and VI–B in table 1 of § 176.170(c) of this chapter: *Provided*, That the temperature of the water or food passing through the resin beds is maintained at 50° C or less and the flow rate of the water or food passing through the beds is not less than 0.5 gallon per cubic foot per minute.

(3) The ion-exchange resin identified in paragraph (a)(17) of this section is used only for industrial application to treat bulk quantities of aqueous food, including potable water, or for treatment of municipal water supplies, subject to the condition that the temperature of the food or water passing through the resin bed is maintained at 25° C or less and the flow rate of the food or water passing through the bed is not less than 2 gallons per cubic foot per minute.

(c) To insure safe use of ion-exchange resins, each ion-exchange resin will be:

(1) Subjected to pre-use treatment by the manufacturer and/or the user in accordance with the manufacturer's directions prescribed on the label or labeling accompanying the resins, to guarantee a food-grade purity of ion-exchange resins, in accordance with good manufacturing practice.

(2) Accompanied by label or labeling to include directions for use consistent with the intended functional purpose of the resin.

(3) Used in compliance with the label or labeling required by paragraph (c)(2) of this section.

(4) Found to result in no more than 1 part per million of organic extractives obtained with each of the named solvents, distilled water, 15 percent alcohol, and 5 percent acetic acid when, having been washed and otherwise treated in accordance with the manufacturer's directions for preparing them for use with food, the ion-exchange resin is subjected to the following test: Using a separate ion-exchange column for each solvent, prepare columns using 50 milliliters of the ready to use ion-exchange resin that is to be tested. While maintaining the highest temperature that will be encountered in use pass through these beds at the rate of 350–450 milliliters per hour the three test solvents distilled water, 15 percent (by volume) ethyl alcohol, and 5 percent (by weight) acetic acid. The first liter of effluent from each solvent is discarded, then the next 2 liters are used to determine organic extractives. The 2-liter sample is carefully evaporated to constant weight at 105° C; this is total extractives. This residue is fired in a muffle furnace at 850° C to constant weight; this is ash. Total extractives. minus ash equals the organic extractives. If the organic extractives are greater than 1 part per million of the solvent used, a blank should be run on the solvent and a correction should be made by subtracting the total extractives obtained with the blank from the total extractives obtained in the resin test. The solvents used are to be made as follows:

Distilled water (de-ionized water is distilled).
15 percent ethyl alcohol made by mixing 15 volumes of absolute ethyl alcohol A.C.S. reagent grade, with 85 volumes of distilled de-ionized water.
5 percent acetic acid made by mixing 5 parts by weight of A.C.S. reagent grade glacial acetic acid with 95 parts by weight of distilled de-ionized water.

In addition to the organic extractives limitation prescribed in this paragraph, the ion-exchange resin identified in paragraph (a)(17) of this section, when extracted with each of the named solvents, distilled water, 50 percent alcohol, and 5 percent acetic acid, will be found to result in not more than 7 parts per million of nitrogen extractives (calculated as nitrogen) when the resin in the free-base form is subjected to the following test immediately before each use: Using a separate 1-inch diameter glass ion-exchange column for each solvent, prepare each column using 100 milliliters of ready to use ion-exchange resin that is to be tested. With the bottom outlet closed, fill each ion-exchange column with one of the three solvents at a temperature of 25° C until the solvent level is even with the top of the resin bed. Seal each column at the top and bottom and store in a vertical position at a temperature of 25° C. After 96 hours, open the top of each column, drain the solvent into a collection vessel, and analyze each drained solvent and a solvent blank for nitrogen by a standard micro-Kjeldahl method.

(d) The ion-exchange resins identified in paragraph (a)(1), (2), (11), and (15) of this section are exempted from the acetic acid extraction requirement of paragraph (c)(4) of this section.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

§ 173.40 Molecular sieve resins.

Molecular sieve resins may be safely used in the processing of food under the following prescribed conditions:

(a) The molecular sieve resins consist of purified devtran having an average molecular weight of 40,000, cross-linked with epichlorohydrin in a ratio of 1 part of dextran to 10 parts of epichlorohydrin, to give a stable three dimensional structure. The resins have a pore size of 2.0 to 3.0 milliliters per gram of dry resin (expressed in terms of water regain), and a particle size of 10 to 300 microns.

(b) The molecular sieve resins are thoroughly washed with potable water prior to their first use in contact with food.

(c) Molecular sieve resins are used as the gel filtration media in the final purification of partially delactosed whey. The gel bed shall be maintained in a sanitary manner in accordance with good manufacturing practice so as to prevent microbial build-up on the bed and adulteration of the product.

§ 173.50 Polyvinylpolypyrrolidone.

The food additive polyvinylpolypyrrolidone may be safely used in accordance with the following prescribed conditions:

(a) The additive is a homopolymer of purified vinylpyrrolidone catalytically produced under conditions producing polymerization and cross-linking such that an insoluble polymer is produced.

(b) The food additive is so processed that when the finished polymer is refluxed for 3 hours with water, 5 percent acetic acid, and 50 percent alcohol, no more than 50 parts per million of extractables is obtained with each solvent.

(c) It is used or intended for use as a clarifying agent in beverages and vinegar, followed by removal with filtration.

§ 173.55 Polyvinylpyrrolidone.

The food additive polyvinylpyrrolidone may be safely used in accordance with the following prescribed conditions:

(a) The additive is a polymer of purified vinylpyrrolidone catalytically produced, having an average molecular weight of 40,000 and a maximum unsaturation of 1 percent, calculated as the monomer, except that the polyvinylpyrrolidone used in beer is that having an average molecular weight of 360,000 and a maximum unsaturation of 1 percent, calculated as the monomer.

(b) The additive is used or intended for use in foods as follows:

Food	Limitations
Beer	As a clarifying agent, at a residual level not to exceed 10 parts per million.
Flavor concentrates in tablet form	As a tableting adjuvent in an amount not to exceed good manufacturing practice.
Nonnutritive sweeteners in concentrated liquid form.	As a stabilizer, bodying agent, and dispersant, in an amount not to exceed good manufacturing practice.
Nonnutritive sweeteners in tablet form.	As a tableting adjuvant in an amount not to exceed good manufacturing practice.
Vitamin and mineral concentrates in liquid form.	As a stabilizer, bodying agent, and dispersant, in an amount not to exceed good manufacturing practice.
Vitamin and mineral concentrates in tablet form.	As a tableting adjuvant in an amount not to exceed good manufacturing practice.
Vinegar	As a clarifying agent, at a residual level not to exceed 40 parts per million.
Wine	As a clarifying agent, at a residual level not to exceed 60 parts per million.

Subpart B—Enzyme Preparations and Microorganisms

§ 173.110 Amyloglucosidase derived from *Rhizopus niveus*.

Amyloglucosidase enzyme product, consisting of enzyme derived from *Rhizopus niveus*, and diatomaceous silica as a carrier, may be safely used in food in accordance with the following conditions:

(a) *Rhizopus niveus* is classified as follows: Class, Phycomycetes; order, Mucorales; family, Mucoraceae; genus, *Rhizopus;* species, *niveus*.

(b) The strain of *Rhizopus niveus* is nonpathogenic and nontoxic in man or other animals.

(c) The enzyme is produced by a process which completely removes the organism *Rhizopus niveus* from the amyloglucosidase.

(d) The additive is used or intended for use for degrading gelatinized starch into constituent sugars, in the production of distilled spirits and vinegar.

(e) The additive is used at a level not to exceed 0.1 percent by weight of the gelatinized starch.

§ 173.120 Carbohydrase and cellulase derived from *Aspergillus niger*.

Carbohydrase and cellulase enzyme preparation derived from *Aspergillus niger* may be safely used in food in accordance with the following prescribed conditions:

(a) *Aspergillus niger* is classified as follows: Class, Deuteromycetes; order, Moniliales; family, Moniliaceae; genus, *Aspergillus;* species, *niger*.

(b) The strain of *Aspergillus niger* is nonpathogenic and nontoxic in man or other animals.

(c) The additive is produced by a process that completely removes the organism *Aspergillus niger* from the carbohydrase and cellulase enzyme product.

(d) The additive is used or intended for use as follows:

(1) For removal of visceral mass (bellies) in clam processing.

(2) As an aid in the removal of the shell from the edible tissue in shrimp processing.

(e) The additive is used in an amount not in excess of the minimum required to produce its intended effect.

§ 173.130 Carbohydrase derived from *Rhizopus oryzae*.

Carbohydrase from *Rhizopus oryzae* may be safely used in the production of dextrose from starch in accordance with the following prescribed conditions:

(a) *Rhizopus oryzae* is classified as follows: Class, Phycomycetes; order, Mucorales; family, Mucoraceae; genus, *Rhizopus;* species, *Rhizopus oryzae*.

(b) The strain of *Rhizopus oryzae* is nonpathogenic and nontoxic.

(c) The carbohydrase is produced under controlled conditions to maintain nonpathogenicity and nontoxicity, including the absence of aflatoxin.

(d) The carbohydrase is produced by a process which completely removes the organism *Rhizopus oryzae* from the carbohydrase product.

(e) The carbohydrase is maintained under refrigeration from production to use and is labeled to include the necessity of refrigerated storage.

§ 173.135 Catalase derived from *Micrococcus lysodeikticus*.

Bacterial catalase derived from *Micrococcus lysodeikticus* by a pure culture fermentation process may be safely used in destroying and removing hydrogen peroxide used in the manufacture of cheese, in accordance with the following conditions.

(a) The organism *Micrococcus lysodeikticus* from which the bacterial catalase is to be derived is demonstrated to be nontoxic and nonpathogenic.

(b) The organism *Micrococcus lysodeikticus* is removed from the bacterial catalase prior to use of the bacterial catalase.

(c) The bacterial catalase is used in an amount not in excess of the minimum required to produce its intended effect.

§ 173.145 Alpha-Galactosidase derived from *Morteirella vinaceae* var. *raffinoseutilizer*.

The food additive alpha-galactosidase and parent mycelial microorganism *Mortierella vinaceae* var. *raffinoseutilizer* may be safely used in food in accordance with the following conditions:

(a) The food additive is the enzyme alpha-galactosidase and the mycelia of the microorganism *Mortierella vinaceae* var. *raffinoseutilizer* which produces the enzyme.

(b) The nonpathogenic microorganism matches American Type Culture Collection (ATCC) No. 20034,[1] and is classified as follows:

Class: Phycomycetes.
Order: Mucorales.
Family: Mortierellaceae.
Genus: *Mortierella*.
Species: *vinaceae*.
Variety: *raffinoseutilizer*.

(c) The additive is used or intended for use in the production of sugar (sucrose) from sugar beets by addition as mycelial pellets to the molasses to increase the yield of sucrose, followed by removal of the spent mycelial pellets by filtration.

(d) The enzyme removal is such that there are no enzyme or mycelial residues remaining in the finished sucrose.

§ 173.150 Milk-clotting enzyme.

Milk-clotting enzyme produced by pure-culture fermentation process may be safely used in the production of cheese in accordance with the following prescribed conditions:

(a) Milk-clotting enzyme is derived from one of the following organisms by a pure-culture fermentation process:

(1) *Endothia parasitica* classified as follows: Class, Ascomycetes; order, Sphaeriales; family, Diaporthacesae; genus, *Endothia;* species, *parasitica*.

(2) *Bacillus cereus* classified as follows: Class, Schizomycetes; order, Eubacteriales; family, Bacillaceae; genus, *Bacillus;* species, *cereus* (Frankland and Frankland).

(3) *Mucor pusillus* Lindt classified as follows: Class, Phycomycetes; subclass, Zygomycetes; order, Mucorales; family, Mucoraceae; genus, *Mucor;* species, *pusillus;* variety, *Lindt*.

(4) *Mucor miehei* Cooney et Emerson classified as follows: Class, Phycomycetes; subclass, Zygomycetes; order, Mucorales; family, Mucoraceae; genus, *Mucor;* species, *miehei;* variety, *Cooney et Emerson*.

(b) The strains of organism identified in paragraph (a) of this section are

[1] Available from: American Type Culture Collection, 12301 Parklawn Drive, Rockville, MD 20852.

nonpathogenic and nontoxic in man or other animals.

(c) The additive is produced by a process that completely removes the generating organism from the milk-clotting enzyme product.

(d) The additive is used in an amount not in excess of the minimum required to produce its intended effect in the production of those cheeses for which it is permitted by standards of identity established pursuant to section 401 of the act.

§ 173.160 *Candida guilliermondii.*

The food additive *Candida guilliermondii* may be safely used as the organism for fermentation production of citric acid in accordance with the following conditions:

(a) The food additive is the enzyme system of the viable organism *Candida guilliermondii* and its concomitant metabolites produced during the fermentation process.

(b)(1) The nonpathogenic and nontoxicogenic organism descending from strain, American Type Culture Collection (ATCC) No. 20474,[12] is classified as follows:

Class: Deuteromycetes.
Order: Moniliales.
Family: Cryptococcaceae.
Genus: *Candida.*
Species: *guilliermondii.*
Variety: *guilliermondii.*

(2) The taxonomic characteristics of the reference culture strain ATCC No. 20474 agree in the essentials with the standard description for *Candida guilliermondii* variety *guilliermondii*, listed in "The Yeasts—A Taxonomic Study," 2d ed., 1970,[13] by Jacomina Lodder.

(c)(1) The additive is used or intended for use as a pure culture in the fermentation process for the production of citric acid using an acceptable aqueous carbohydrate substrate.

(2) The organism *Candida guilliermondii* is made nonviable and is completely removed from the citric acid during the recovery and purification process.

(d) The additive is so used that the citric acid produced conforms to the specifications of the "Food Chemicals Codex," 2d ed., 1972.[11]

§ 173.165 *Candida lipolytica.*

The food additive *Candida lipolytica* may be safely used as the organism for fermentation production of citric acid in accordance with the following conditions:

(a) The food additive is the enzyme system of the organism *Candida lipolytica* and its concomitant metabolites produced during the fermentation process.

(b) (1) The nonpathogenic organism is classified as follows:

Class: Deuteromycetes.
Order: Moniliales.
Family: Cryptococcaceae.
Genus: *Candida.*
Species: *lipolytica.*

(2) The taxonomic characteristics of the culture agree in the essentials with the standard description for *Candida lipolytica* variety *lipolytica*, listed in *The Yeasts—A Taxonomic Study*, 2d Ed. (1970)[13] by Jacomina Lodder.

(c) The additive is used or intended for use as a pure culture in the fermentation process for the production of citric acid from purified normal alkanes.

(d) The additive is so used that the citric acid produced conforms to the specifications of the Food Chemicals Codex, 2d Ed. (1972)[11] and meet the following ultraviolet absorbance limits when subjected to the analytical procedure described in this paragraph:

Ultraviolet absorbance per centimeter path length:	*Maximum*
280 to 289 millimicrons	0.25
290 to 299 millimicrons	0.20
300 to 359 millimicrons	0.13
360 to 400 millimicrons	0.03

ANALYTICAL PROCEDURE FOR CITRIC ACID

GENERAL INSTRUCTIONS

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of citric acid samples in handling is essential to assure absence of any extraneous material arising from inadequate packaging. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

1. Aluminum foil, oil free.

2. Separatory funnels, 500-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

3. Chromatographic tubes: (a) 80-millimeter ID x 900-millimeter length equipped with tetrafluoroethylene polymer stopcock and course fritted disk; (b) 18-millimeter ID x 300-millimeter length equipped with tetrafluoroethylene polymer stopcock.

4. Rotary vacuum evaporator, Buchi or equivalent.

5. Spectrophotometer—Spectral range 250–400 nanometers with spectral slit width of 2 nanometers or less; under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Wavelength repeatability, ±0.2 nanometer.

Wavelength accuracy, ±1.0 nanometer.

The spectrophotometer is equipped with matched 1 centimeter path length quartz microcuvettes with 0.5-milliliter volume capacity.

6. Vacuum oven, minimum inside dimensions: 200 mm x 200 mm x 300 mm deep.

REAGENTS AND MATERIALS

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The methyl alcohol, isooctane, benzene, hexane and 1,2-dichloroethane designated in the list following this paragraph shall pass the following test:

The specified quantity of solvent is added to a 250-milliliter round bottom flask containing 0.5 milliliter of purified *n*-hexadecane and evaporated on the rotary evaporator at 45° C to constant volume. Six milliliters of purified isooctane are added to this residue and evaporated under the same conditions as above for 5 minutes. Determine the absorbance of the residue compared to purified *n*-hexadecane as reference. The absorbance of the solution of the solvent residue shall not exceed 0.03 per centimeter path length between 280 and 299 nanometers and 0.01 per centimeter path length between 300 and 400 nanometers.

Methyl alcohol, A.C.S. reagent grade. Use 100 milliliters for the test described in the preceding paragraph. If necessary, methyl alcohol may be purified by distillation through a Virgreaux column discarding the first and last ten percent of the distillate or otherwise.

Benzene, spectrograde (Burdick and Jackson Laboratories, Inc., Muskegon, Mich., or equivalent). Use 80 milliliters for the test. If necessary, benzene may be purified by distillation or otherwise.

Isooctane (2,2,4-trimethylpentane). Use 100 milliliters for the test. If necessary, isooctane may be purified by passage through a column of activated silica gel, distillation or otherwise.

Hexane, spectrograde (Burdick and Jackson Laboratories, Inc., Muskegon, Mich., or equivalent). Use 100 milliliters for the test. If necessary, hexane may be purified by distillation or otherwise.

1,2-Dichloroethane, spectrograde (Matheson, Coleman and Bell, East Rutherford, N.J., or equivalent). Use 100 milliliters for the test. If necessary, 1,2-dichloroethane may be purified by distillation or otherwise.

ELUTING MIXTURES

1. *10 percent 1,2-dichloroethane in hexane.* Prepare by mixing the purified solvents in the volume ratio of 1 part of 1,2-dichloroethane to 9 parts of hexane.

2. *40 percent benzene in hexane.* Prepare by mixing the purified solvents in the volume ratio of 4 parts of benzene to 6 parts of hexane.

n-Hexadecane, 99 percent olefin-free. Determine the absorbance compared to isooctane as reference. The absorbance per centimeter path length shall not exceed 0.00 in the range of 280–400 nanometers. If necessary, *n*-hexadecane may be purified by percolation through activated silica gel, distillation or otherwise.

Silica gel, 28–200 mesh (Grade 12, Davison Chemical Co., Baltimore, MD, or equivalent). Activate as follows: Slurry 900 grams of silica gel reagent with 2 liters of purified water in a 3-liter beaker. Cool the mixture and pour into a 80 x 900 chromatographic column with coarse fritted disc. Drain the water, wash with an additional 6 liters of purified water and wash with 3,600 milliliters of purified methyl alcohol at a relatively slow rate. Drain all of the solvents and transfer the silica gel to an aluminum foil-lined drying dish. Place foil over the top of the dish. Activate in a vacuum oven at low vacuum (approximately 750 millimeters Mercury or 27 inches of Mercury below atmospheric pressure) at 173° to 177° C for at

[11] Copies may be obtained from: The National Academy of Sciences, 2101 Constitution Ave. NW., Washington, D.C. 20037.

[12] Available from: American Type Culture Collection, 12301 Parklawn Drive, Rockville, MD 20852.

[13] Copies may be obtained from: Director, Division of Food and Color Additives, Bureau of Foods, 200 C St. SW., Washington, D.C. 20204.

least 20 hours. Cool under vacuum and store in an amber bottle.

Sodium sulfate, anhydrous, A.C.S. reagent grade. This reagent should be washed with purified isooctane. Check the purity of this reagent as described in § 172.886 of this chapter.

Water, purified. All water used must meet the specifications of the following test:

Extract 600 milliliters of water with 50 milliliters of purified isooctane. Add 1 milliliter of purified *n*-hexadecane to the isooctane extract and evaporate the resulting solution to 1 milliliter. The absorbance of this residue shall not exceed 0.02 per centimeter path length between 300–400 nanometers and 0.03 per centimeter path length between 280–299 nanometers. If necessary, water may be purified by distillation, extraction with purified organic solvents, treatment with an absorbent (e.g., activated carbon) followed by filtration of the absorbent or otherwise.

PROCEDURE

Separate portions of 200 milliliters of purified water are taken through the procedure for use as control blanks. Each citric acid sample is processed as follows: Weigh 200 grams of anhydrous citric acid into a 500 milliliter flask and dissolve in 200 milliliters of pure water. Heat the solution to 60° C and transfer to a 500 milliliter separatory funnel. Rinse the flask with 50 milliliters of isooctane and add the isooctane to the separatory funnel. Gently shake the mixture 90 times (caution: vigorous shaking will cause emulsions) with periodic release of the pressure caused by shaking.

Allow the phases to separate for at least 5 minutes. Draw off the lower aqueous layer into a second 500-milliliter separatory funnel and repeat the extraction with a second aliquot of 50 milliliters of isooctane. After separation of the layers, draw off and discard the water layer. Combine both isooctane extracts in the funnel containing the first extract. Rinse the funnel which contained the second extract with 10 milliliters of isooctane and add this portion to the combined isooctane extract.

A chromatographic column containing 5.5 grams of silica gel and 3 grams of anhydrous sodium sulfate is prepared for each citric acid sample as follows: Fit 18 x 300 column with a small glass wool plug. Rinse the inside of the column with 10 milliliters of purified isooctane. Drain the isooctane from the column. Pour 5.5 grams of activated silica gel into the column. Tap the column approximately 20 times on a semisoft, clean surface to settle the silica gel. Carefully pour 3 grams of anhydrous sodium sulfate onto the top of the silica gel in the column.

Carefully drain the isooctane extract of the citric acid solution into the column in a series of additions while the isooctane is draining from the column at an elution rate of approximately 3 milliliters per minute. Rinse the separatory funnel with 10 milliliters of isooctane after the last portion of the extract has been applied to the column and add this rinse to the column. After all of the extract has been applied to the column and the solvent layer reaches the top of the sulfate bed, rinse the column with 25 milliliters of isooctane followed by 10 milliliters of a 10-percent dichloroethane in hexane solution. For each rinse solution, drain the column until the solvent layer reaches the top of the sodium sulfate bed. Discard the rinse solvents. Place a 250-milliliter round bottom flask containing 0.5 milliliter of purified *n*-hexadecane under the column. Elute the polynuclear aromatic hydrocarbons from the column with 30 milliliters of 40-percent benzene in hexane solution. Drain the eluate until the 40-percent benzene in the hexane solvent reaches the top of the sodium sulfate bed.

Evaporate the 40-percent benzene in hexane eluate on the rotary vacuum evaporator at 45° C until only the *n*-hexadecane residue of 0.5 milliliter remains. Treat the *n*-hexadecane residue twice with the following wash step: Add 6 milliliters of purified isooctane and remove the solvents by vacuum evaporation at 45° C to constant volume, i.e., 0.5 milliliter. Cool the *n*-hexadecane residue and transfer the solution to an 0.5-milliliter microcuvette. Determine the absorbance of this solution compared to purified *n*-hexadecane as reference. Correct the absorbance values for any absorbance derived from the control reagent blank. If the corrected absorbance does not exceed the limits prescribed, the samples meet the ultraviolet absorbance specifications.

The reagent blank is prepared by using 200 milliliters of purified water in place of the citric acid solution and carrying the water sample through the procedure. The typical control reagent blank should not exceed 0.03 absorbance per centimeter path length between 280 and 299 nanometers, 0.02 absorbance per centimeter path length between 300 and 359 nanometers, and 0.01 absorbance per centimeter path length between 360 and 400 nanometers.

Subpart C—Solvents, Lubricants, Release Agents and Related Substances

§ 173.210 Acetone.

A tolerance of 30 parts per million is established for acetone in spice oleoresins when present therein as a residue from the extraction of spice.

§ 173.220 1,3-Butylene glycol.

1,3-Butylene glycol (1,3-butanediol) may be safely used in food in accordance with the following prescribed conditions:

(a) The substance meets the following specifications:

(1) 1,3-Butylene glycol content: Not less than 99 percent.

(2) Specific gravity at 20/20° C: 1.004 to 1.006.

(3) Distillation range: 200°–215° C.

(b) It is used in the minimum amount required to perform its intended effect.

(c) It is used as a solvent for natural and synthetic flavoring substances except where standards of identity issued under section 401 of the act preclude such use.

§ 173.230 Ethylene dichloride.

A tolerance of 30 parts per million is established for ethylene dichloride in spice oleoresins when present therein as a residue from the extraction of spice; *Provided, however,* That if residues of other chlorinated solvents are also present the total of all residues of such solvents shall not exceed 30 parts per million.

§ 173.240 Isopropyl alcohol.

Isopropyl alcohol may be present in the following foods under the conditions specified:

(a) In spice oleoresins as a residue from the extraction of spice, at a level not to exceed 50 parts per million.

(b) In lemon oil as a residue in production of the oil, at a level not to exceed 6 parts per million.

(c) In hops extract as a residue from the extraction of hops at a level not to exceed 2.0 percent by weight: *Provided,* That,

(1) The hops extract is added to the wort before or during cooking in the manufacture of beer.

(2) The label of the hops extract specifies the presence of the isopropyl alcohol and provides for the use of the hops extract only as prescribed by paragraph (c)(1) of this section.

§ 173.250 Methyl alcohol residues.

Methyl alcohol may be present in the following foods under the conditions specified:

(a) In spice oleoresins as a residue from the extraction of spice, at a level not to exceed 50 parts per million.

(b) In hops extract as a residue from the extraction of hops, at a level not to exceed 2.2 percent by weight; *Provided,* That:

(1) The hops extract is added to the wort before or during cooking in the manufacture of beer.

(2) The label of the hops extract specifies the presence of methyl alcohol and provides for the use of the hops extract only as prescribed by paragraph (b)(1) of this section.

§ 173.255 Methylene chloride.

Methylene chloride may be present in food under the following conditions:

(a) In spice oleoresins as a residue from the extraction of spice, at a level not to exceed 30 parts per million; *Provided,* That, if residues of other chlorinated solvents are also present, the total of all residues of such solvents shall not exceed 30 parts per million.

(b) In hops extract as a residue from the extraction of hops, at a level not to exceed 2.2 percent, *Provided,* That:

(1) The hops extract is added to the wort before or during cooking in the manufacture of beer.

(2) The label of the hops extract identifies the presence of the methylene chloride and provides for the use of the hops extract only as prescribed by paragraph (b)(1) of this section.

(c) In coffee as a residue from its use as a solvent in the extraction of caffeine from green coffee beans, at a level not to exceed 10 parts per million (0.001 percent) in decaffeinated roasted coffee and in decaffeinated soluble coffee extract (instant coffee).

§ 173.270 Hexane.

Hexane may be present in the following foods under the conditions specified:

(a) In spice oleoresins as a residue from the extraction of spice, at a level not to exceed 25 parts per million.

(b) In hops extract as a residue from the extraction of hops, at a level not to exceed 2.2 percent by weight; *Provided,* That:

(1) The hops extract is added to the wort before or during cooking in the manufacture of beer.

(2) The label of the hops extract specifies the presence of the hexane and provides for the use of the hops extract only as prescribed by paragraph (b)(1) of this section.

§ 173.275 Hydrogenated sperm oil.

The food additive hydrogenated sperm oil may be safely used in accordance with the following prescribed conditions:

(a) The sperm oil is derived from rendering the fatty tissue of the sperm whale or is prepared by synthesis of fatty acids and fatty alcohols derived from the sperm whale. The sperm oil obtained by rendering is refined. The oil is hydrogenated.

(b) It is used alone or as a component of a release agent or lubricant in bakery pans.

(c) The amount used does not exceed that reasonably required to accomplish the intended lubricating effect.

§ 173.280 Solvent extraction process for citric acid.

A solvent extraction process for recovery of citric acid from conventional *Aspergillus niger* fermentation liquor may be safely used to produce food-grade citric acid in accordance with the following conditions:

(a) The solvent used in the process consists of a mixture of *n*-octyl alcohol meeting the requirements of § 172.864 of this chapter, synthetic isoparaffinic petroleum hydrocarbons meeting the requirements of § 172.882 of this chapter, and tridodecyl amine.

(b) The component substances are used solely as a solvent mixture and in a manner that does not result in formation of products not present in conventionally produced citric acid.

(c) The citric acid so produced meets the specifications of the Food Chemicals Codex, 2d Ed. (1972)[1] and supplements thereto, and the polynuclear aromatic hydrocarbon specifications of § 173.165.

(d) Residues of *n*-octyl alcohol and synthetic isoparaffinic petroleum hydrocarbons are removed in accordance with good manufacturing practice. Current good manufacturing practice results in residues not exceeding 16 parts per million (ppm) *n*-octyl alcohol and 0.47 ppm synthetic isoparaffinic petroleum hydrocarbons in citric acid.

(e) Tridodecyl amine may be present as a residue in citric acid at a level not to exceed 100 parts per billion.

(Secs. 201(s), 409, 710(a), 52 Stat. 1055, 72 Stat. 1784–1788, as amended (21 U.S.C. 321(s), 348, 371(a)).)

§ 173.290 Trichloroethylene.

Tolerances are established for residues of trichloroethylene resulting from its use as a solvent in the manufacture of foods as follows:

Decaffeinated ground coffee.	25 parts per million.
Decaffeinated soluble (instant) coffee extract.	10 parts per million.
Spice oleoresins	30 parts per million (provided that if residues of other chlorinated solvents are also present, the total of all residues of such solvents in spice oleoresins shall not exceed 30 parts per million).

Subpart D—Specific Usage Additives

§ 173.310 Boiler water additives.

Boiler water additives may be safely used in the preparation of steam that will contact food, under the following conditions:

(a) The amount of additive is not in excess of that required for its functional purpose, and the amount of steam in contact with food does not exceed that required to produce the intended effect in or on the food.

(b) The compounds are prepared from substances identified in paragraphs (c) and (d) of this section, and are subject to the limitations, if any, prescribed:

(c) List of substances:

	Limitations
Acrylamide-sodium acrylate resin	Contains not more than 0.05 percent by weight of acrylamide monomer.
Ammonium alginate	
Cobalt sulfate (as catalyst)	
Lignosulfonic acid	
Monobutyl ethers of polyethylene-polypropylene glycol produced by random condensation of a 1:1 mixture by weight of ethylene oxide and propylene oxide with butanol.	Minimum mol. wt. 1,500.
Polyethylene glycol	As defined in § 172.820 of this chapter.
Polyoxypropylene glycol	Do.
Potassium carbonate	
Potassium tripolyphosphate	
Sodium acetate	
Sodium alginate	
Sodium aluminate	
Sodium carbonate	
Sodium carboxymethylcellulose	Contains not less than 95 percent sodium carboxymethylcellulose on a dry-weight basis, with maximum substitution of 0.9 carboxymethyl groups per anhydroglucose unit, and with a minimum viscosity of 15 centipoises for 2 percent by weight aqueous solution at 25° C; such determinations to be made by methods prescribed in Food Chemicals Codex (Second Edition) [1] monograph for sodium carboxymethyl-cellulose.
Sodium glucoheptonate	Less than 1 part per million cyanide in the sodium glucoheptonate.
Sodium hexametaphosphate	
Sodium humate	
Sodium hydroxide	
Sodium lignosulfonate	
Sodium metasilicate	
Sodium metabisulfite	
Sodium nitrate	
Sodium phosphate (mono-, di-, tri-)	
Sodium polyacrylate	
Sodium polymethacrylate	
Sodium silicate	
Sodium sulfate	
Sodium sulfite (neutral or alkaline)	
Sodium tripolyphosphate	
Tannin (including quebracho extract)	
Tetrasodium EDTA	
Tetrasodium pyrophosphate	

(d) Substances used alone or in combination with substances in paragraph (c) of this section:

	Limitations
Cyclohexylamine	Not to exceed 10 parts per million in steam, and excluding use of such steam in contact with milk and milk products.
Diethylaminoethanol	Not to exceed 15 parts per million in steam, and excluding use of such steam in contact with milk and milk products.
Hydrazine	Zero in steam.
Morpholine	Not to exceed 10 parts per million in steam, and excluding use of such steam in contact with milk and milk products.
Octadecylamine	Not to exceed 3 parts per million in steam, and excluding use of such steam in contact with milk and milk products.
Trisodium nitrilotriacetate	Not to exceed 5 parts per million in boiler feedwater; not to be used where steam will be in contact with milk and milk products.

[1] Copies may be obtained from: The National Academy of Sciences, 2101 Constitution Ave. NW., Washington, D.C. 20037.

(e) To assure safe use of the additive, in addition to the other information required by the act, the label or labeling shall bear:

(1) The common or chemical name or names of the additive or additives.

(2) Adequate directions for use to assure compliance with all the provisions of this section.

§ 173.315 Chemicals used in washing or to assist in the lye peeling of fruits and vegetables.

Chemicals may be safely used to wash or to assist in the lye peeling of fruits and vegetables in accordance with the following conditions:

(a) The chemicals consist of one or more of the following:

(1) Substances generally recognized as safe in food or covered by prior sanctions for use in washing fruits and vegetables.

(2) Substances identified in this subparagraph and subject to such limitations as are provided:

Substances	*Limitations*
A mixture of alkylene oxide adducts of alkyl alcohols and phosphate esters of alkylene oxide adducts of alkyl alcohols consisting of: α-alkyl (C_{12}-C_{18})-*omega*-hydroxy-poly (oxyethylene) (7.5–8.5 moles)/poly (oxypropylene) block copolymer having an average molecular weight of 810; α-alkyl (C_{12}-C_{18})-*omega*-hydroxy-poly (oxyethylene) (3.3–3.7 moles) polymer having an average molecular weight of 380, and subsequently esterified with 1.25 moles phosphoric anhydride; and α-alkyl (C_{16}-C_{18})-*omega*-hydroxypoly (oxyethylene) (11.9–12.9 moles)/poly (oxypropylene) copolymer, having an average molecular weight of 810, and subsequently esterified with 1.25 moles phosphoric anhydride.	May be used at a level not to exceed 0.2 percent in lye-peeling solution to assist in the lye peeling of fruits and vegetables.
Aliphatic acid mixture consisting of valeric, caproic, enanthic, caprylic, and pelargonic acids.	May be used at a level not to exceed 1 percent in lye-peeling solution to assist in the lye peeling of fruits and vegetables.
Polyacrylamide	Not to exceed 10 p.p.m. in wash water. Contains not more than 0.2 percent acrylamide monomer.
Potassium bromide	Not to exceed 0.2 percent in wash water. May be used in washing or to assist in the lye peeling of fruits and vegetables.
Sodium *n*-alkylbenzene-sulfonate (alkyl group predominantly C_{13} and C_{14} and not less than 95 percent C_{12} to C_{16}).	Do.
Sodium dodecylbenzene-sulfonate (alkyl group predominantly C_{12} and not less than 95% C_{10} to C_{14}).	Do.
Sodium 2 ethyl-hexyl sulfate	
Sodium hypochlorite	
Sodium mono- and di-methyl naphthalene sulfonates (mol. wt. 245–260).	Not to exceed 0.2 percent in wash water. May be used in the washing or to assist in the lye peeling of fruits and vegetables.

(b) The chemicals are used in amounts not in excess of the minimum required to accomplish their intended effect.

(c) The use of the chemicals is followed by rinsing with potable water to remove, to the extent possible, residues of the chemicals.

(d) To assure safe use of the additive:

(1) The label and labeling of the additive container shall bear, in addition to the other information required by the act, the name of the additive or a statement of its composition.

(2) The label or labeling of the additive container shall bear adequate use directions to assure use in compliance with all provisions of this section.

§ 173.320 Chemical for controlling microorganisms in cane-sugar and beet-sugar mills.

The food additives disodium cyanodithioimidocarbonate, disodium ethylenebisdithiocarbamate, ethylenediamine, potassium *N*-methyldithiocarbamate, and sodium dimethyldithiocarbamate may be safely used in accordance with the following conditions:

(a) They are used in the control of microorganisms in cane-sugar and/or beet-sugar mills as specified in paragraph (b) of this section.

(b) They are applied to the sugar mill grinding system in one of the combinations listed in paragraph (b) (1), (2), or (3) of this section. Quantities of the individual additives in parts per million are expressed in terms of the weight of raw cane or raw beets.

(1) Combination for cane-sugar mills:

	Parts per million
Disodium cyanodithioimidocarbonate	2.5
Ethylenediamine	1.0
Potassium *N*-methyldithiocarbamate	3.5

(2) Combination for cane-sugar mills:

	Parts per million
Disodium ethylenebisdithiocarbamate	3.0
Sodium dimethyldithiocarbamate	3.0

(3) Combinations for cane-sugar mills and beet-sugar mills:

	Parts per million
(i) Disodium ethylenebisdithiocarbamate	3.0
Ethylenediamine	2.0
Sodium dimethyldithiocarbamate	3.0
(ii) Disodium cyanodithioimidocarbonate	2.9
Potassium *N*-methyldithiocarbamate	4.1

(c) To assure safe use of the additives, their label and labeling shall conform to that registered with the Environmental Protection Agency.

§ 173.340 Defoaming agents.

Defoaming agents may be safely used in processing foods, in accordance with the following conditions:

(a) They consist of one or more of the following:

(1) Substances generally recognized by qualified experts as safe in food or covered by prior sanctions for the use prescribed by this section.

(2) Substances listed in this paragraph (a)(2) of this section, subject to any limitations imposed:

Substances	Limitations
Dimethylpolysiloxane (substantially free from hydrolyzable chloride and alkoxy groups; no more than 18 percent loss in weight after heating 4 hours at 200° C; viscosity 300–600 centistokes at 25° C; refractive index 1.400–1.404 at 25° C).	10 parts per million in food, or at such level in a concentrated food that when prepared as directed on the label the food in its ready-for-consumption state will have not more than 10 parts per million except as follows: Zero in milk; 110 parts per million in dry gelatin dessert mixes labeled for use whereby no more than 16 parts per million is present in the ready-to-serve dessert; 250 parts per million in salt labeled for cooking purposes, whereby no more than 10 parts per million is present in the cooked food.
Formaldehyde	As a preservative in defoaming agents containing dimethylpolysiloxane, in an amount not exceeding 1.0 percent of the dimethylpolysiloxane content.
Polyacrylic acid, sodium salt	As a stabilizer and thickener in defoaming agents containing dimethylpolysiloxane in an amount reasonably required to accomplish the intended effect.
Polyethylene glycol	As defined in § 172.820 of this chapter.
Polyoxyethylene 40 monostearate	As defined in U.S.P. XVI.
Polysorbate 60	As defined in § 172.836 of this chapter.
Polysorbate 65	As defined in § 172.838 of this chapter.
Propylene glycol alginate	As defined in § 172.858 of this chapter.
Silicon dioxide	As defined in § 172.480 of this chapter.
Sorbitan monostearate	As defined in § 172.842 of this chapter.
White mineral oil: Conforming with § 172.878 of this chapter.	As a component of defoaming agents for use in wash water for sliced potatoes at a level not to exceed 0.008 percent of the wash water.

(3) Substances listed in this paragraph (a)(3), provided they are components of defoaming agents limited to use in processing beet sugar and yeast, and subject to any limitations imposed:

Substances	Limitations
Aluminum stearate	As defined in § 172.863 of this chapter.
Butyl stearate	As an antioxidant, not to exceed 0.1 percent by weight of defoamer.
BHA	
BHT	As an antioxidant, not to exceed 0.1 percent by weight of defoamer.
Calcium stearate	As defined in § 172.863 of this chapter.
Fatty acids	As defined in § 172.860 of this chapter.
Formaldehyde	As a preservative.
Hydroxylated lecithin	As defined in § 172.814 of this chapter.
Isopropyl alcohol	
Magnesium stearate	As defined in § 172.863 of this chapter.
Mineral oil: Conforming with § 172.878 of this chapter.	
Oderless light petroleum hydrocarbons: Conforming with § 172.884 of this chapter.	
Petrolatum: Conforming with § 172.880 of this chapter.	Not more than 150 p.p.m. in yeast, measured as hydrocarbons.
Petroleum wax: Conforming with § 172.886 of this chapter.	
Petroleum wax, synthetic	
Synthetic isoparaffinic petroleum hydrocarbons: Conforming with § 172.862 of this chapter.	
Oleic acid derived from tall oil fatty acids	Complying with § 172.862 of this chapter.
Oxystearin	As defined in § 172.818 of this chapter.
Polyoxyethylene (600) dioleate	
Polyoxyethylene (600) monoricinoleate	Molecular weight range, 1,200–2,500.
Polypropylene glycol	As defined in § 172.840 of this chapter.
Polysorbate 80	As defined in § 172.863 of this chapter.
Potassium stearate	As defined in § 172.856 of this chapter.
Propylene glycol mono- and diesters of fats and fatty acids.	
Soybean oil fatty acids, hydroxylated	
Tallow, hydrogenated, oxidized or sulfated	
Tallow alcohol, hydrogenated	

(4) The substance listed in this paragraph (a)(4), provided it is a component of defoaming agents limited to use in processing beet sugar only, and subject to the limitations imposed:

Substance	Limitations
n-Butoxypolyoxyethylene polyoxypropylene glycol.	Molecular weight range, 3,900–4,100 (hydroxyl determination).

(b) They are added in an amount not in excess of that reasonably required to inhibit foaming.

§ 173.345 Chloropentafluoroethane.

The food additive chloropentafluoroethane may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive has a purity of not less than 99.97 percent, and contains not more than 200 parts per million saturated fluoro compounds and 10 parts per million unsaturated fluoro compounds as impurities.

(b) The additive is used or intended for use alone or with one or more of the following substances: Carbon dioxide, nitrous oxide, propane, and octafluorocyclobutane complying with § 173.360, as a propellant and aerating agent for foamed or sprayed food products except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive:

(1) The label of the food additive container shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive, chloropentafluoroethane, with or without the parenthetical name "Food Propellant 115".

(ii) The percentage of the additive present in the case of a mixture.

(iii) The designation "food grade".

(2) The label or labeling of the food additive container shall bear adequate directions for use.

§ 173.350 Combustion product gas.

The food additive combustion product gas may be safely used in the processing and packaging of the foods designated in paragraph (c) of this section for the purpose of removing and displacing oxygen in accordance with the following prescribed conditions:

(a) The food additive is manufactured by the controlled combustion in air of butane, propane, or natural gas. The combustion equipment shall be provided with an absorption-type filter capable of removing possible toxic impurities, through which all gas used in the treatment of food shall pass; and with suitable controls to insure that any combustion products failing to meet the specifications provided in this section will be prevented from reaching the food being treated.

(b) The food additive meets the following specifications:

(1) Carbon monoxide content not to exceed 4.5 percent by volume.

(2) The ultraviolet absorbance in isooctane solution in the range 255 millimicrons to 310 millimicrons not to exceed one-third of the standard reference absorbance when tested as described in paragraph (e) of this section.

(c) It is used or intended for use to displace or remove oxygen in the processing, storage, or packaging of beverage products and other food, except fresh meats.

(d) To assure safe use of the additive in addition to the other information required by the act, the label or labeling of the combustion device shall bear adequate directions for use to provide a combustion product gas that complies with the limitations prescribed in paragraph (b) of this section, including instructions to assure proper filtration.

(e) The food additive is tested for compliance with paragraph (b)(2) by the following empirical method:

Spectrophotometric measurements. All measurements are made in an ultraviolet spectrophotometer in optical cells of 5 centimeters in length, and in the range of 255 millimicrons to 310 millimicrons, under the same instrumental conditions. The standard reference absorbance is the absorbance at 275 millimicrons of a standard reference solution of naphthalene (National Bureau of Standards Material No. 577 or equivalent in purity) containing a concentration of 1.4 milligrams per liter in purified isooctane, measured against isooctane of the same spectral purity in 5-centimeter cells. (This absorbance will be approximately 0.30.)

Solvent. The solvent used is pure grade isooctane having an ultraviolet absorbance not to exceed 0.05 measured against distilled water as a reference. Upon passage of purified inert gas through some isooctane under the identical conditions of the test, a lowering of the absorbance value has been observed. The absorbance of isooctane to be used in this procedure shall not be more than 0.02 lower in the range 255 millimicrons to 310 millimicrons, inclusive, than that of the untreated solvent as measured in a 5-centimeter cell. If necessary to obtain the prescribed purities, the isooctane may be passed through activated silica gel.

Apparatus. To assure reproducible results, the additive is passed into the isooctane solution through a gas-absorption train consisting of the following components and necessary connections:

1. A gas flow meter with a range up to 30 liters per hour provided with a constant differential relay or other device to maintain a constant flow rate independent of the input pressure.

2. An absorption apparatus consisting of an inlet gas dispersion tube inserted to the bottom of a covered cylindrical vessel with a suitable outlet on the vessel for effluent gas. The dimensions and arrangement of tube and vessel are such that the inlet tube introduces the gas at a point not above 5¼ inches below the surface of the solvent through a sintered glass outlet. The dimensions of the vessel are such, and both inlet and vessel are so designed, that the gas can be bubbled through 60 milliliters of isooctane solvent at a rate up to 30 liters per hour without mechanical loss of solvent. The level corresponding to 60 milliliters should be marked on the vessel.

3. A cooling bath containing crushed ice and water to permit immersion of the absorption vessel at least to the solvent level mark.

Caution. The various parts of the absorption train must be connected by gastight tubing and joints composed of materials which will neither remove components from nor add components to the gas stream. The gas source is connected in series to the flow-rate device, the flow meter, and the absorption apparatus in that order. Ventilation should be provided for the effluent gases which may contain carbon monoxide.

Sampling procedure. Immerse the gas-absorption apparatus containing 60 milliliters of isooctane in the coolant bath so that the solvent is completely immersed. Cool for at least 15 minutes and then pass 120 liters of the test gas through the absorption train at a rate of 30 liters per hour or less. Maintain the coolant bath at 0° C throughout. Remove the absorption vessel from the bath, disconnect, and warm to room temperature. Add isooctane to bring the contents of the absorption vessel to 60 milliliters, and mix. Determine the absorbance of the solution in the 5-centimeter cell in the range 255 millimicrons to 310 millimicrons, inclusive, compared to isooctane. The absorbance of the solution of combustion product gas shall not exceed that of the isooctane solvent at any wavelength in the specified range by more than one-third of the standard reference absorbance.

§ 173.355 Dichlorofluoromethane.

The food additive dichlorodifluoromethane may be safely used in food in accordance with the following prescribed conditions:

(a) The additive has a purity of not less than 99.97 percent.

(b) It is used or intended for use, in accordance with good manufacturing practice, as a direct-contact freezing agent for foods.

(c) To assure safe use of the additive:

(1) The label of its container shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive, dichlorodifluoromethane, with or without the parenthetical name "Food Freezant 12".

(ii) The designation "food grade".

(2) The label or labeling of the food additive container shall bear adequate directions for use.

§ 173.360 Octafluorocyclobutane.

The food additive octafluorocyclobutane may be safely used as a propellant and aerating agent in foamed or sprayed food products in accordance with the following conditions:

(a) The food additive meets the following specifications:

99.99 percent octafluorocyclobutane.
Less than 0.1 part per million fluoroolefins, calculated as perfluoroisobutylene.

(b) The additive is used or intended for use alone or with one or more of the following substances: Carbon dioxide, nitrous oxide, and propane, as a propellant and aerating agent for foamed or sprayed food products, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive:

(1) The label of the food additive container shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive, octafluorocyclobutane.

(ii) The percentage of the additive present in the case of a mixture.

(iii) The designation "food grade".

(2) The label or labeling of the food additive container shall bear adequate directions for use.

§ 173.385 Sodium methyl sulfate.

Sodium methyl sulfate may be present in pectin in accordance with the following conditions.

(a) It is present as the result of methylation of pectin by sulfuric acid and methyl alcohol and subsequent treatment with sodium bicarbonate.

(b) It does not exceed 0.1 percent by weight of the pectin.

PART 174—INDIRECT FOOD ADDITIVES: GENERAL

Sec.
174.5 General provisions applicable to indirect food additives.

AUTHORITY: Sec. 409, 72 Stat. 1785-1786 as amended (21 U.S.C. 348, 371).

§ 174.5 General provisions applicable to indirect food additives.

(a) Regulations prescribing conditions under which food additive substances may be safely used predicate usage under conditions of good manufacturing practice. For the purpose of this part and Parts 175, 176, and 177 of this chapter, good manufacturing practice shall be defined to include the following restrictions:

(1) The quantity of any food additive substance that may be added to food as a result of use in articles that contact food shall not exceed, where no limits are specified, that which results from use of the substance in an amount not more than reasonably required to accomplish the intended physical or technical effect in the food-contact article; shall not exceed any prescribed limitations; and shall not be intended to accomplish any physical or technical effect in the food itself, except as such may be permitted by regulations in Parts 170 through 189 of this chapter.

(2) Any substance used as a component of articles that contact food shall be of a purity suitable for its intended use.

(b) The existence in the Subchapter B of a regulation prescribing safe conditions for the use of a substance as an article or component of articles that contact food shall not be construed to relieve such use of the substance or article from compliance with any other provision of the Federal Food, Drug, and Cosmetic Act. For example, if a regulated food-packaging material were found on appropriate test to impart odor or taste to a specific food product such as to render it unfit within the meaning of section 402(a)(3) of the act, the regulation would not be construed to relieve such use from compliance with section 402(a)(3).

(c) The existence in this Subchapter B of a regulation prescribing safe conditions for the use of a substance as an article or component of articles that contact food shall not be construed as implying that such substance may be safely used as a direct additive in food.

(d) Substances that under conditions of good manufacturing practice may be safely used as components of articles that contact food include the following, subject to any prescribed limitations:

(1) Substances generally recognized as safe in or on food.

(2) Substances generally recognized as safe for their intended use in food packaging.

(3) Substances used in accordance with a prior sanction or approval.

(4) Substances permitted for use by regulations in this part and Parts 175, 176, 177, 178 and § 179.45 of this chapter.

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVE COATINGS AND COMPONENTS

Subpart A—[Reserved]

Subpart B—Substances for Use Only as Components of Adhesives

Sec.
175.105 Adhesives.
175.125 Pressure-sensitive adhesives.

Subpart C—Substances for Use as Components of Coatings

175.210 Acrylate ester copolymer coatings.
175.230 Hot-melt strippable food coatings.
175.250 Paraffin (synthetic).
175.260 Partial phosphoric acid esters of polyester resins.
175.270 Poly(vinyl fluoride) resins.
175.300 Resinous and polymeric coatings.
175.320 Resinous and polymeric coatings for polyolefin films.
175.350 Vinyl acetate/crotonic acid copolymer.
175.360 Vinylidene chloride copolymer coatings for nylon film.
175.365 Vinylidene chloride copolymer coatings for polycarbonate film.
175.380 Xylene-formaldehyde resins condensed with 4,4'-isopropylidenediphenol-epichlorohydrin epoxy resins.

Sec.
175.390 Zinc-silicon dioxide matrix coatings.

AUTHORITY: Secs. 409, 701, 52 Stat. 1055–1056 as amended, 72 Stat. 1785–1788 as amended (21 U.S.C. 348, 371), unless otherwise noted.

Subpart A—[Reserved]

Subpart B—Substances for Use Only as Components of Adhesives

§ 175.105 Adhesives.

(a) Adhesives may be safely used as components of articles intended for use in packaging, transporting, or holding food in accordance with the following prescribed conditions:

(1) The adhesive is prepared from one or more of the optional substances named in paragraph (c) of this section, subject to any prescribed limitations.

(2) The adhesive is either separated from the food by a functional barrier or used subject to the following additional limitations:

(i) *In dry foods.* The quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice.

(ii) *In fatty and aqueous foods.* (*a*) The quantity of adhesive that contacts packaged fatty and aqueous foods shall not exceed the trace amount at seams and at the edge exposure between packaging laminates that may occur within the limits of good manufacturing practice.

(*b*) Under normal conditions of use the packaging seams or laminates will remain firmly bonded without visible separation.

(b) To assure safe usage of adhesives, the label of the finished adhesive container shall bear the statement "food-packaging adhesive".

(c) Subject to any limitation prescribed in this section and in any other regulation promulgated under section 409 of the act which prescribes safe conditions of use for substances that may be employed as constituents of adhesives, the optional substances used in the formulation of adhesives may include the following:

(1) Substances generally recognized as safe for use in food or food packaging.

(2) Substances permitted for use in adhesives by prior sanction or approval and employed under the specific conditions of use prescribed by such sanction or approval.

(3) Flavoring substances permitted for use in food by regulations in this part, provided that such flavoring substances are volatilized from the adhesives during the packaging fabrication process.

(4) Color additives approved for use in food.

(5) Substances permitted for use in adhesives by other regulations in this subchapter and substances named in this subparagraph: *Provided, however,* That any substance named in this subparagraph and covered by a specific regulation in this subchapter, must meet any specifications in such regulation.

Substances	*Limitations*
Abietic acid	
Acetone	
Acetone-urea-formaldehyde resin	
N-Acetyl ethanolamine	
Acetyl tributyl citrate	
Acetyl triethyl citrate	
Albumin, blood	
4-[2-[2-(2-alkoxy (C_{12}–C_{18}) ethoxy) ethoxyl) ethyl) disodium sulfosuccinate.	
1-Alkyl (C_8—C_{18}) amino-3-amino-propane monoacetate	
Alkylated (C_4 and/or C_8) phenols	
Alkyl (C_7–C_{12}) benzene	
Alkyl (C_{16}–C_{20}) dimethylbenzyl ammonium chloride	
n-Alkyl(C_{12}, C_{14}, C_{16}, or C_{18}) dimethyl (ethylbenzyl) ammonium cyclohexylsulfamate.	For use as preservative only.
Alkyl ketenedimers as described in § 176.120 of this chapter.	
Alkyl (C_7–C_{12}) naphthalene	
3-amino-propane diol	For use only in the preparation of polyurethane resins.
Aluminum	
Aluminum acetate	
Aluminum di(2-ethylhexoate)	
Aluminum potassium silicate	
N-β-Aminoethyl-*gamma*-aminopropyl trimethoxysilane	
3-(Aminomethyl)-3,5,5-trimethyl-cyclohexylamine	
Aminomethylpropanol	For use as preservative only.
Ammonium benzoate	For use only as bonding agent for aluminum foil, stabilizer or preservative. Total fluoride from all sources not to exceed 1 percent by weight of the finished adhesive.
Ammonium bifluoride	
Ammonium borate	
Ammonium citrate	
Ammonium persulfate	
Ammonium polyacrylate	
Ammonium potassium hydrogen phosphate	
Ammonium silico-fluoride	For use only as bonding agent for aluminum foil, stabilizer, or preservative. Total fluoride from all sources not to exceed 1 percent by weight of the finished adhesive.
Ammonium sulfamate	
Ammonium thiocyanate	
Ammonium thiosulfate	
Amyl acetate	
Anhydroenneaheptitol	
Animal glue as described in § 178.3120 of this chapter	
2-Anthraquinone sulfonic acid, sodium salt	For use only as polymerization-control agent.
Antimony oxide	
Asbestos	
Asphalt, paraffinic and naphthenic	
Azelaic acid	
Azo-*bis*-isobutyronitrile	
Balata rubber	
Barium acetate	
Barium peroxide	
Barium sulfate	
Bentonite	
Benzene (benzol)	
Benzothiazyldisulfide	
p-Benzoxyphenol	For use as preservative only.
Benzoyl peroxide	
Benzyl alcohol	
Benzyl benzoate	
Benzyl bromoacetate	For use as preservative only.
p-Benzyloxyphenol	For use as preservative only.
BHA (butylated hydroxyanisole)	
BHT (butylated hydroxytoluene)	
Bicyclo[2.2.1]hept-2-ene-6-methyl acrylate	
2-Biphenyl diphenyl phosphate	
1,3-Bis(2-benzothiazolylmercaptomethyl) urea	
4,4'-Bis(α,α-dimethylbenzyl)diphenylamine	
2,6-Bis (1-methylheptadecyl)-p-cresol	
Bis(tri-*n*-butyltin) oxide	For use as preservative only.
Bis(trichloromethyl)sulfone C.A. Registry No. 3064708	For use as a preservative only.
Borax	
Boric acid	
1,3-Butanediol	
1,4-Butanediol	
1,4-Butanediol modified with adipic acid	
Butoxy polyethylene polypropylene glycol (molecular weight 900-4,200).	
Butyl acetate	
Butyl acetyl ricinoleate	
Butyl alcohol	
Butylated, styrenated cresols identified in § 178.2010 (b) of this chapter.	
Butyl benzoate	
Butyl benzyl phthalate	
Butyldecyl phthalate	
1,3-Butylene glycoldiglycolic acid copolymer	
tert-Butyl hydroperoxide	
4,4'-Butylidenebis(6-*tert*-butyl-*m*-cresol)	
Butyl lactate	
Butyloctyl phthalate	
p-*tert*-Butylphenyl salicylate	
Butyl phthalate butyl glycolate	
p-*tert*-Butylpyrocatechol	For use only as polymerization-control agent.
Butyl ricinoleate	
Butyl rubber polymer	
Butyl stearate	
Butyl titanate, polymerized	
Butyraldehyde	
Calcium ethyl acetoacetate	
Calcium nitrate	
Calcium metasilicate	
Camphor	
Camphor fatty acid esters	
Candelilla wax	
epsilon-Caprolactam-(ethylene-ethyl acrylate) graft polymer.	
Carbon black, channel process	

Substances	Limitations
Carbon disulfide-1,1'-methylenedipiperidine reaction product.	
Carbon tetrachloride	
Carboxymethylcellulose	
Castor oil, polyoxyethylated (4–84 moles ethylene oxide)	
Cellulose acetate butyrate	
Cellulose acetate propionate	
Ceresin wax (ozocerite)	
Cetyl alcohol	
Chloracetamide	
Chloral hydrate	
Chlorinated liquid *n*-paraffins with chain lengths of C_{18}–C_{27}, containing 40–70 percent chlorine by weight.	
Chlorinated pyridine mixture with active ingredients consisting of 2,3,5,6-tetrachloro-4-(methylsulfonyl) pyridine, 2,3,5,6-tetrachloro-4-(methylsulfinyl) pyridine and pentachloropyridine.	For use as preservative only.
Chlorinated rubber polymer (natural rubber polymer containing approximately 67 percent chlorine).	
1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	For use as preservative only.
Chlorobenzene	
4-Chloro-3,5-dimethylphenol (*p*-chloro-*m*-xylenol)	For use as preservative only.
4-Chloro-3-methylphenol	For use as preservative only.
Chloroform	
Chloroprene	
Chromium caseinate	
Chromium nitrate	
Chromium potassium sulfate	
Cobaltous acetate	
Coconut fatty acid amine salt of tetrachlorophenol	For use as preservative only.
Copal	
Copper 8-quinolinolate	For use as preservative only.
Coumarone-indene resin	
Cresyl diphenyl phosphate	
Cumene hydroperoxide	
Cyanoguanidine	
Cyclized rubber as identified in § 176.170(b)(3) of this chapter	
Cyclohexane	
Cyclohexanol	
Cyclohexanone resin	
Cyclohexanone-formaldehyde condensate	
N-Cyclohexyl *p*-toluene sulfonamide	
Damar	
Defoaming agents as described in § 176.210 of this chapter.	
Dehydroacetic acid	
Diacetone alcohol	
Diacetyl peroxide	
N,N'-Dialkoyl-4,4'-diaminodiphenylmethane mixtures where the alkoyl groups are derived from marine fatty acids (C_{12}–C_{24}).	
2,5-Di-*tert*-amylhydroquinone	
Diamines derived from dimerized vegetable oil acids	
Diaryl-*p*-phenylenediamine, where the aryl group may be phenyl tolyl, or xylyl.	
Di(butoxyethyl) phthalate	
2,5-Di-*tert*-butylhydroquinone	
Dibutyl maleate	
2,6-Di-*tert*-butyl-4-methylphenol	For use as preservative only.
Di(C_7, C_9-alkyl)adipate	
Dibutyl phthalate	
Dibutyl sebacate	
Dibutyltin dilaurate for use only as a catalyst for polyurethane resins.	
1, 2-Dichloroethylene (mixed isomers)	
Dicumyl peroxide	
Dicyclohexyl phthalate	
Diethanolamine	
Diethanolamine condensed with animal or vegetable fatty acids.	
Diethylamine	
Diethylene glycol	
Diethylene glyco-adipic acid copolymer	
Diethylene glycol dibenzoate	
Diethylene glycol hydrogenated tallowate monoester	
Diethylene glycol laurate	
Diethylene glycol monobutyl ether	
Diethylene glycol monobutyl ether acetate	
Diethylene glycol monoethyl ether	
Diethylene glycol monoethyl ether acetate	
Diethylene glycol monomethyl ether	
Diethylene glycol monooleate	
Diethylene glycol monophenyl ether	
Diethylene glycol copolymer of adipic acid and phthalic anhydride.	
Di(2-ethylhexyl) adipate	
Di(2-ethylhexyl) hexahydrothalate	
Di(2-ethylhexy)phthalate	
Diethyl oxalate	
Diethyl phthalate	
Dihexyl phthalate	
Dihydroabietylphthalate	
Di(2-hydroxy-5-*tert*-butylphenyl) sulfide	
2,2'-Dihydroxy-5,5'-dichlorodiphenyimethane (dichlorophene).	
4,5-Dihydroxy-2-imidazolidinone	
4-(Diiodomethylsulfonyl)toluene CA Registry No.: 20018-09-01.	For use as an antifungal preservative only.
Diisobutyl adipate	
Diisobutyl ketone	
Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride.	
Diisobutyl phthalate	
Diisodecyl adipate	
Diisodecyl phthalate	
Diisooctyl phthalate	
Diisopropylbenzene hydroperoxide	
N,N-Dimethylcyclohexylamine dibutyldithiocarbamate	
Dimethyl formamide	
Dimethyl hexynol	
2,2-Dimethyl-1,3-propanediol dibenzoate	

Substances	Limitations
Dimethyl oxtynediol	
N-(1,1-dimethyl-3-ocobutyl) acrylamide	
Dimethyl phthalate	
3,5-Dimethyl-1,3,5,2*H*-tetrahydrothiadiazine-2-thione	For use as preservative only.
Di-β-naphthyl-*p*-phenylenediamine	
4,6-Dinonyl-*o*-cresol	
Dinonylphenol	
Di-*n*-octyldecyl adipate	
Dioctyldiphenylamine	
Dioctylphthalate	
Dioctylsebacate	
Dioxane	
Dipentaerythritol pentastearate	
Dipentamethylene-thiuram-tetrasulfide	
Dipentene	
Dipentene resins	
Diphenyl-2-ethylhexyl phosphate	
Diphenyl, hydrogenated	
N,N'-Diphenyl-*p*-phenylenediamine	
Diphenyl phthalate	
1,3-Diphenyl-2-thiourea	
Dipropylene glycol	
Dipropylene glycol dibenzoate	
Dipropylene glycol monomethyl ether	
Dipropylene glycol copolymer of adipic acid and phthalic anhydride.	
Disodium cyanodithioimidocarbonate	
N,N'-Distearoylethylenediamine	
Distearyl thiodipropionate	
4,4'-Dithiodimorpholine	
n-Dodecylmercaptan	
tert-Dodecylmercaptan	
Dodecylphenoxybenzene-disulfonic acid and/or its calcium, magnesium, and sodium salts.	
Elemi gum	
Epichlorohydrin-4,4'-isopropylidenediphenol resin	
Epichlorohydrin-4,4'-*sec*-butylidenediphenol resin	
Epichlorohydrin-4,4'-isopropylidene-di-*o*-cresol resin	
Epichlorohydrin-phenolformaldehyde resin	
Erucamide (erucylamide)	
Ethanolamine	
Ethoxypropanol butyl ether	
Ethyl alcohol (ethanol)	
Ethylenediamine	
Ethylenediaminetetra-acetic acid, calcium, ferric, potassium, or sodium salts, single or mixed.	
Ethylene dichloride	
Ethylene glycol	
Ethylene glycol monobutyl ether	
Ethylene glycol monobutyl ether acetate	
Ethylene glycol monoethyl ether	
Ethylene glycol monoethyl ether acetate	
Ethylene glycol monoethyl ether ricinoleate	
Ethylena glycol monomethyl ether	
Ethylene glycol monophenyl ether	
Ethylene-maleic anhydride copolymer, ammonium or potassium salt.	
Ethylene-methacrylic acid copolymer partial salts: Ammonium, calcium, magnesium, sodium, and/or zinc.	
Ethylene-methacrylic acid-vinyl acetate copolymer partial salts: Ammonium, calcium, magnesium, sodium, and/or zinc.	
Ethylene-propylene-dicyclopentadiene copolymer rubber.	
Ethylene, propylene, 1,4-hexadiene and 2,5-norbornadiene tetrapolymer.	
Ethyl-*p*-hydroxybenzoate	For use as preservative only.
Ethyl hydroxyethylcellulose	
Ethyl lactate	
Ethyl phthalyl ethyl glycolate	
Ethyl-*p*-toluene sulfonamide	
Fats and oils derived from animal or vegetable sources, and the hydrogenated, sulfated, or sulfonated forms of such fats and oils.	
Fatty acids derived from animal or vegetable fats and oils; and salts of such acids, single or mixed, as follows:	
Aluminum	
Ammonium	
Calcium	
Magnesium	
Potassium	
Sodium	
Zinc	
Ferric chloride	
Fluosilicic acid (hydrofluosilicic acid)	For use only as bonding agent for aluminum foil, stabilizer, or preservative. Total fluoride from all sources not to exceed 1 percent by weight of the finished adhesive.
Formaldehyde	
Formaldehyde *o*- and *p*-toluene sulfonamide	
Formamide	
Fumaratochromium (III) nitrate	
Furfural	
Furfuryl alcohol	
Fumaric acid	
Glutaraldehyde	
Glycerides, di- and monoesters	
Glyceryl borate (glycol boriborate resin)	
Glyceryl ester of damar, copal, elemi, and sandarac	
Glyceryl monobutyl ricinoleate	
Glyceryl monohydroxy stearate	
Glyceryl monohydroxy tallowate	
Glyceryl polyoxypropylene triol (average molecular weight 1,000).	
Glyceryl tribenzoate	
Glycol diacetate	
Glyoxal	
Heptane	
Hexamethylenetetramine	
Hexane	
Hexanetriols	

Substances	Limitations
Hexylene glycol	
Hydroabietyl alcohol	
Hydrofluoric acid	For use only as bonding agent for aluminum foil, stabilizer, or preservative. Total fluoride from all sources not to exceed 1 percent by weight of the finished adhesive.
Hydrogen peroxide	
α-Hydro-*omega*-hydroxypoly-(oxytetramethylene)	For use only in the preparation of polyurethane resins.
Hydroquinone	
Hydroquinone monobenzyl ether	
Hydroquinone monoethyl ether	
2(2′-Hydroxy-3′,5′ di-*tert*-amylphenyl) benzotriazole	
Hydroxyacetic acid	
7-Hydroxycoumarin	
Hydroxyethylcellulose	
1-(2-Hydroxyethyl)-1-(4-chlorobutyl)-2 alkyl (C_8–C_{17}) imidazolinium chloride.	
Hydroxyethyldiethylene-triamine	
β-Hydroxyethyl pyridinium 2-mercaptobenzothiazol	
Hydroxyethyl starch	
Hydroxyethylurea	
Hydroxylamine sulfate	
Hydroxypropyl methylcellulose	
2-(Hydroxymethyl)-2-methyl-1,3-propane-diol tribenzoate.	
2-Imidazolidinone	
Iodoform	For use only as polymerization-control agent.
Isoascorbic acid	
Isobuytl alcohol (isobutanol)	
Isobutylene-isoprene copolymer	
Isophorone	
Isopropanolamine (mono-, di-, tri-)	
Isopropyl acetate	
Isopropyl alcohol (isopropanol)	
Isopropyl-*m*- and *p*-cresol (thymol derived)	
4 4′-Isopropylidenedi-phenol	
4,4′-Isopropylidenedi-phenol, polybutylated mixture	
Isopropyl peroxydicarbonate	For use as preservative only.
p-Isopropoxy diphenylamine	
4,4′-Isopropylidene-bis(*p*-phenyleneoxy)-di-2-propanol	
Itaconic acid	
Japan wax	
Kerosene	
Lauroyl peroxide	
Lauroyl sulfate salts:	
Ammonium	
Magnesium	
Potassium	
Sodium	
Lauryl alcohol	
Lauryl pyridinium 5-chloro-2-mercaptobenzothiazole	
Lignin calcium sufonate	
Lignin sodium sulfonate	
Linoleamide (linoleic acid amide)	
Magnesium fluoride	For use only as bonding agent for aluminum foil, stabilizer, or preservative. Total fluoride from all sources not to exceed 1 percent by weight of the finished adhesives.
Magnesium glycerophosphate	
Maleic acid	
Maleic anhydride-diisobutylene copolymer, ammonium or sodium salt.	
Manganese acetate	
Marine oil fatty acid soaps, hydrogenated	
Melamine	
Melamine-formaldehyde copolymer	
2-Mercaptobenzothiazole	
2-Mercaptobenzothiazole and dimethyl dithiocarbamic acid mixture, sodium salt.	For use as preservative only.
2-Mercaptobenzothiazole, sodium or zinc salt	For use as preservative only.
Methacrylate-chromic chloride complex, ethyl or methyl ester.	
p-Menthane hydroperoxide	
Methyl acetate	
Methyl acetyl ricinoleate	
Methyl alcohol (methanol)	
Methylcellulose	
Methylene chloride	
4,4′-Methylenebis(2,6-di-*tert*-butylphenol)	
2,2-Methylenebis (4-ethyl-6-*tert*-butylphenol)	
2,2-Methylenebis (4-methyl-6-nonylphenol)	
2,2-Methylenebis (4-methyl-6-*tert*-butylphenol)	
Methyl ethyl ketone	
Methyl ethyl ketone-formaldehyde condensate	
2-Methylhexane	
1-Methyl-2-hydroxy-4-isopropyl benzene	
Methyl isobutyl ketone	
Methyl oleate	
Methyl oleate-palmitate mixture	
Methyl phthalyl ethyl glycolate	
Methyl ricinoleate	
Methyl salicylate	
α-Methylstyrene-vinyltoluene copolymer resins (molar ratio 1 α methylstyrene to 3 vinyltoluene).	
Methyl tallowate	
Mineral oil	
Monochloracetic acid	
Monooctyldiphenylamine	
Montan wax	
Morpholine	
Myristic acid-chromic chloride complex	
Myristyl alcohol	
Naphtha	
Naphthalene, monosulfonated	
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt.	
α-Naphthylamine	
α,α′, α″, α‴-Neopentane tetrayltetrakis [*omega*-hydroxypoly (oxypropylene) (1–2 moles)], average molecular weight 400.	
Nitric acid	
o-Nitrobiphenyl	

Substances	Limitations
Nitrocellulose	
2-Nitropropane	
α-(*p*-Nonylphenyl)-*omega*-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters; the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content averages 6–9 moles or 50 moles.	
α-(*p*-Nonylphenyl)-*omega*-hydroxypoly (oxyethylene) produced by the condensation of 1 mole of *p*-nonylphenol (nonyl group is a propylene trimer isomer) with an average of 1–40 moles of ethylene oxide.	
α-(*p*-Nonylphenyl)-*omega*-hydroxypoly (oxyethylene) sulfate, ammonium salt; the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content averages 9 or 30 moles.	
endo-cis-5-Norbornene-2,3-dicarboxylic anhydride	
α-*cis*-9-Octadecenyl-*omega*-hydroxypoly (oxyethylene); the octadecenyl group is derived from oleyl alcohol and the poly (oxyethylene) content averages 20 moles.	
Octadecyl 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate	
Octyl alcohol	
Octyldecyl phthalate	
Octylphenol	
Octylphenoxyethanols	
Octylphenoxypolyethoxy-polypropoxyethanol (13 moles of ethylene oxide and propylene oxide).	
Odorless light petroleum hydrocarbons	
Oleamide (oleic acid amide)	
Oleic acid, sulfated	
Oxazoline	
2-Oxydiethylene-benzothiazole	
Palmitamide (palmitic acid amide)	
Paraffin (C_{12}–C_{30}) sulfonate	
Paraformaldehyde	
Pentachlorophenol	
Pentaerythritol ester of maleic anhydride	
Pentaerythritol monostearate	For use as preservative only.
Pentaerythritol tetrabenzoate [CAS Registry No. 4196-86-5].	
Pentaerythritol tetrastearate	
2,4-Pentanedione	
Perchloroethylene	
Petrolatum	
Petroleum hydrocarbon resin (cyclopentadiene type), hydrogenated.	
Petroleum hydrocarbon resin (produced by the catalytic polymerization and subsequent hydrogenation of styrene, vinyltoluene, and indene types from distillates of cracked petroleum stocks).	
Petroleum hydrocarbon resins (produced by the homo- and copolymerization of dienes and olefins of the aliphatic, alicyclic, and monobenzenoid arylalkene types from distillates of cracked petroleum stocks).	
Phenol	For use as a preservative only.
Phenol-coumarone-indene resin	
Phenolic resins as described in § 175.300 (b)(3)(vi)	
Phenothiazine	For use only as polymerization-control agent.
Phenyl-β-naphthylamine (free of β-naphthylamine)	For use as preservative only.
o-Phenylphenol	
o-Phthalic acid	
Pimaric acid	
Pine oil	
Piperazine	
Piperidinium pentamethylenedithiocarbamate	
Polyamides derived from reaction of one or more of the following acids with one or more of the following amines:	
Acids:	
Azelaic acid	
Dimerized vegetable oil acids	
Amines:	
Bis(hexamethylene) triamine and higher homologues	
Diethylenetriamine	
Diphenylamine	
Ethylenediamine	
Hexamethylenediamine	
Tetraethylenepentamine	
Triethylenetetramine	
Polybutene, hydrogenated	
Polybutylene glycol (molecular weight 1,000)	
Poly [2(diethylamino) ethyl methacrylate] phosphate	
Polyester of adipic acid, phthalic acid, and propylene glycol, terminated with butyl alcohol.	
Polyester of diglycolic acid and propylene glycol containing ethylene glycol monobutyl ether as a chain stopper.	
Polyester resins (including alkyd type), as the basic polymer, formed as esters when one or more of the following acids are made to react with one or more of the following alcohols:	
Poly(oxycaproyl) diols and triols (minimum molecular weight 500).	
Acids:	
Azelaic acid	
Polybasic and monobasic acids identified in § 175.300(b)(3)(vii) (*a*) and (*b*).	
Tetrahydrophthalic acid.	
Alcohols:	
1,4-Cyclohexanedimethanol.	
2,2-Dimethyl-1,3-propanediol.	
Polyhydric and monohydric alcohols identified in § 175.300(b)(3)(vii) (*c*) and (*d*).	
Polyethyleneadipate modified with ethanolamine with the molar ratio of the amine to the adipic acid less than 0.1 to 1.	For use only in the preparation of polyurethan resins.
Polyethylene glycol (molecular weight 200–6,000)	
Polyethylene, oxidized	
Polyethylene resins, carboxyl modified, identified in § 177.1600 of this chapter.	
Polyethylenimine	
Polyethylenimine-epicholrohydrin resins	
Polyisoprene	

Substances	*Limitations*
Polymeric esters of polyhydric alcohols and polycarboxylic acids prepared from glycerin and phthalic anhydride and modified with benzoic acid, castor oil, coconut oil, linseed oil, rosin, soybean oil, styrene, and vinyl toluene.	
Polymers: Homopolymers and copolymers of the following monomers:	
Acrylamide	
Acrylic acid	
Acrylonitrile	
Butadiene	
Butene	
N-tert-Butylacrylamide	
Butyl acrylate	
1,3-Butylene glycol dimethacrylate	
Butyl methacrylate	
Crotonic acid	
Decyl acrylate	
Diallyl fumarate	
Diallyl maleate	
Diallyl phthalate	
Dibutyl fumarate	
Dibutyl itaconate	
Dibutyl maleate	
Di(2-ethylhexyl) maleate	
Dimethyl-α-methylstyrene	
Dioctyl fumarate	
Dioctyl mateate	
Divinylbenzene	
Ethyl acrylate	
Ethylene	
Ethylene cyanohydrin	
2-Ethylhexyl acrylate	
Ethyl methacrylate	
Fumaric acid and/or its methyl, ethyl propyl, butyl, amyl hexyl, heptyl and octyl esters.	
Glycidyl methacrylate	
2-Hydroxyethyl acrylate	
2-Hydroxyethyl methacrylate	
2-Hydroxypropyl methacrylate	
Isobutyl acrylate	
Isobutylene	
Itaconic acid	
Maleic acid, diester with 2-hydroxyethanesulfonic acid, sodium salt.	
Maleic anhydride	
Methacrylic acid	
Methyl acrylate	
N,N'-Methylenebisacrylamide	
Methyl methacrylate	
N-Methylolacrylamide	
Methyl styrene	
Monoethyl maleate	
Monomethyl maleate	
Mono (2-ethylhexyl) maleate	
5-Norbornene-2 3-dicarboxylic acid, mono-*n*-butyl ester	
Propyl acrylate	
Propylene	
Styrene	
Triallyl cyanurate	
Vinyl acetate	
Vinly alcohol (from alcoholysis or hydrolysis of vinyl acetate units).	
Vinyl butyrate	
Vinyl chloride	
Vinyl crotonate	
Vinyl ethyl ether	
Vinyl hexoate	
Vinylidene chloride	
Vinyl methyl ether	
Vinyl pelargonate	
Vinyl propionate	
Vinyl pyrrolidone	
Vinyl stearate	
Polyoxyalkylated-phenolic resin (phenolic resin obtained from formaldehyde plus butyl- and/or amylphenols, oxyalkylated with ethylene oxide and/or propylene oxide).	
Polyoxyethylated (40 moles) tallow alcohol sulfate, sodium salt.	
Polyoxyethylene (molecular weight 200) dibenzoate	
Polyoxyethylene (molecular weight 200–600) esters of fatty acids derived from animal or vegetable fats and oils (including tall oil).	
Polyoxyethylene (15 moles) ester of rosin	
Polyoxyethylene (4–5 moles) ether of phenol	
Polyoxyethylene (25 moles)—glycerol adduct	
Polyoxyethylene (40 moles) stearate	
Polyoxyethylene (5–15 moles) tridecyl alcohol	
Polyoxypropylene (3 moles) tridecyl alcohol sulfate	
Polyoxypropylene (20 moles) butyl ether	
Polyoxypropylene (40 moles) butyl ether	
Polyoxypropylene (20 moles) oleate butyl ether	
Polyoxypropylene-polyoxyethylene condensate (minimum molecular weight 1,900).	
Polypropylene glycol (minimum molecular weight 150)	
Polypropylene glycol (3–4 moles) triether with 2-ethyl-2-(hydroxymethyl)-1,3-propane-diol, average molecular weight 730.	
Polypropylene, noncrystalline	
Polysiloxanes:	
Diethyl polysiloxane	
Dihydrogen polysiloxane	
Dimethyl polysiloxane	
Diphenyl polysiloxane	
Ethyl hydrogen polysiloxane	
Ethyl phenyl polysiloxane	
Methyl ethyl polysiloxane	
Methyl hydrogen polysiloxane	
Methyl phenyl polysiloxane	
Phenyl hydrogen polysiloxane	

Substances	*Limitations*
Polysorbate 60	
Polysorbate 80	
Polysorbate 20 (polyoxyethylene (20) sorbitan monolaurate).	
Polysorbate 40 (polyoxyethylene (20) sorbitan monopalmitate).	
Poly[styrene-co-disodium maleate-co-α-(*p*-nonyl phenyl)-*omega*-(*p*-vinyl-benzyl)poly(oxyethylene)] terpolymer.	
Polytetrafluoroethylene	
Polyurethane resins produced by reacting diisocyanates with one or more of the polyols or polyesters named in this subparagraph or produced by reacting the chloroformate derivatives of one or more of the polyols or polyesters named in this subparagraph with one or more of the polyamines named in this subparagraph.	
Polyvinyl alcohol modified so as to contain not more than 3 weight percent of comonomer units derived from 1-alkenes having 12 to 20 carbon atoms.	
Polyvinyl butyral	
Polyvinyl formal	
Potassium ferricyanide	For use only as polymerization-control agent.
Potassium *N*-methyldithiocarbamate	
Potassium pentachlorophenate	For use as preservative only.
Potassium permanganate	
Potassium persulfate	
Potassium phosphates (mono-, di-, tribasic)	
Potassium tripolyphosphate	
α, α′, α″-1, 2, 3-Propanetriyltris [omega-(2, 3-epoxypropoxy) poly (oxypropylene) (24 moles)].	
β-Propiolactone	
Propyl alcohol (propanol)	
Propylene carbonate	
Propylene glycol and p-p′-isopropylidenediphenol diether.	
Propylene glycol esters of coconut fatty acids	
Propylene glycol monolaurate	
Propylene glycol monomethyl ether	
Propylene glycol monostearate	
α, α′, α″-[Propylidynetris (methylene)] tris [*omega*-hydroxypoly (oxypropylene) (1.5 moles minimum)], minimum molecular weight 400.	
Quaternary ammonium chloride (hexadecyl, octadecyl derivative).	For use as preservative only.
Rosin (wood, gum, and tall oil rosin), rosin dimers, decarboxylated rosin (including rosin oil, disproportionated rosin, and these substances as modified by one or more of the following reactants:	
Alkyl (C_1–C_8) phenolformaldehyde	
Ammonia	
Ammonium caseinate-*p*-Cyclohexylphenolformaldehyde.	
Diethylene glycol	
Dipentaerythritol	
Ethylene glycol	
Formaldehyde	
Fumaric acid	
Glycerin	
Hydrogen	
Isophthalic acid	
4,4′-Isopropylidenediphenol-epichlorohydrin (epoxy)	
4,4′-Isopropylidenediphenol-formaldehyde	
Maleic anhydride	
Methyl alcohol	
Pentaerythritol	
Phthalic anhydride	
Polyethylene glycol	
Phenol-formaldehyde	
Phenyl *o*-cresol-formaldehyde	
p-Phenylphenol-formaldehyde	
Sulfuric acid	
Triethylene glycol	
Xylenol-formaldehyde	
Rosin salts (salts of wood, gum, and tall oil rosin, and the dimers thereof, decarboxylated rosin disproportionated rosin, hydrogenated rosin):	
Aluminum	
Ammonium	
Calcium	
Magnesium	
Potassium	
Sodium	
Zinc	
Rosin, gasoline-insoluble fraction	
Rubber hydrochloride polymer	
Rubber latex, natural	
Salicylic acid	For use as preservative only.
Sandarac	
Sebacic acid	
Shellac	
Silicon dioxide as defined in § 172.480(a) of this chapter.	
Silicon dioxide as defined in Sec. 121.1958(a)	
Sodium alkyl (C_7–C_{13} aliphatic) benezenesulfonate	
Sodium aluminum pyrophosphate	
Sodium aluminum sulfate	
Sodium bisulfate	
Sodium calcium silicate	
Sodium capryl polyphosphate	
Sodium carboxymethylcellulose	
Sodium chlorate	
Sodium chlorite	
Sodium chromate	
Sodium decylsulfate	
Sodium dehydroacetate	For use as preservative only.
Sodium di-(2-ethylhexoate)	
Sodium di-(2-ethylhexyl) pyrophosphate	
Sodium dihexylsulfosuccinate	
Sodium diisobutylphenoxydiethoxyethyl sulfonate	
Sodium diisobutylphenoxymonoethoxyethyl sulfonate	

Substances	*Limitations*
Sodium diisopropyl- and triisopropylnaphthalenesulfonate.	
Sodium dimethyldithiocarbamate	
Sodium dioctylsulfosuccinate	
Sodium *n*-dodecylpolyethoxy (50 moles) sulfate	
Sodium ethylene ether of nonylphenol sulfate	
Sodium 2-ethylhexyl sulfate	
Sodium fluoride	For use only as bonding agent for aluminum foil, stabilizer, or preservative. Total fluoride for all sources not to exceed 1 percent by weight of the finished adhesive.
Sodium formaldehyde sulfoxylate	
Sodium formate	
Sodium heptadecylsulfate	
Sodium hypochlorite	
Sodium isododecylphenoxypolyethoxy (40 moles) sulfate	
Sodium *N*-lauroyl sarcosinate	
Sodium metaborate	
Sodium α-naphthalene sulfonate	
Sodium nitrate	
Sodium nitrite	
Sodium oleoyl isopropanolamide sulfosuccinate	
Sodium pentachlorophenate	For use as preservative only.
Sodium perborate	
Sodium persulfate	
Sodium o-phenylphenate	For use as preservative only.
Sodium polyacrylate	
Sodium polymethacrylate	
Sodium polystyrene sulfonate	
Sodium salicylate	For use as preservative only.
Sodium salt of 1-hydroxy 2(1H)-pyridine thione	For use as preservative only.
Sodium tetradecylsulfate	
Sodium thiocyanate	
Sodium bis-tridecylsulfosuccinate	
Sodium xylene sulfonate	
Sorbitan monooleate	
Sorbitan monostearate	
Soybean oil, epoxidized	
Spermaceti wax	
Sperm oil wax	
Stannous 2-ethylhexanoate	For use only as a catalyst for polyurethane resins.
Stannous stearate	
Starch hydrolysates	
Starch or starch modified by one or more of the treatments described in §§ 172.892 and 178.3520 of this chapter.	
Starch, reacted with a urea-formaldehyde resin	
Starch, reacted with formaldehyde	
Stearamide (stearic acid amide)	
Stearic acid	
Stearic acid-chromic chloride complex	
Stearyl-cetyl alcohol, technical grade, approximately 65 percent–80 percent stearyl and 20 percent–35 percent cetyl.	
Strontium salicylate	
Styrenated phenol	
Styrene block polymers with 1,3-butadiene	
Styrene-maleic anhydride copoylmer, ammonium or potassium salt.	
Styrene-maleic anhydride copolymer (partially methylated) sodium salt.	
Styrene-methacrylic acid copolymer, potassium salt	
Sucrose acetate isobutyrate	
Sucrose benzoate	
Sucrose octaacetate	
α-Sulfo-omega-(dodecyloxy)poly (oxyethylene), ammonium salt.	
Sulfonated octadecylene (sodium form)	
Sulfur	
Tall oil	
Tall oil fatty acids, linoleic and oleic	
Tall oil fatty acid methyl ester	
Tall oil, methyl ester	
Tall oil pitch	
Tall oil soaps	
Tallow alcohol (hydrogenated)	
Tallow amine, secondary (hexadecyl, octadecyl), of hard tallow.	
Tallow, blown (oxidized)	
Tallow, propylene glycol ester	
Terpene resins (α-and β-pinene) homopolymers, copolymers, and condensates with phenol, formaldehyde, coumarone, and/or indene.	
Terphenyl	
Terphenyl, hydrogenated	
Terpineol	
Tetraethylene pentamine	
Tetraethylthiuram disulfide	
Tetrahydrofuran	
Tetrahydrofurfuryl alcohol	
Tetra-isopropyl titanate	
α-[p-(1,1,3,3-Tetramethylbutyl) phenyl]-*omega*-hydroxypoly-(oxyethylene) produced by the condensation of 1 mole of *p*-(1,1,3,3-tetramethylbutyl) phenol with an average of 1–40 moles of ethylene oxide.	
Tetrakis[methylene (3,5-di-*tert*-butyl-4-hydroxy-hydrocinnamate)] methane.	
α-[p-(1,1,3,3-Tetramethylbutyl) phenyl]-*omega*-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and their sodium, potassium, and ammonium salts having a poly(oxyethylene) content averaging 6–9 or 40 moles.	
Tetramethyl decanediol	
Tetramethyl decynediol	
Tetramethyl decynediol plus 1–30 moles of ethylene oxide.	
Tetramethylthiuram monosulfide	
Tetrasodium *N*-(1,2-dicarboxyethyl)-*N*-octadecylsulfosuccinamate.	
4,4'-Thiobis-6-*tert*-butyl-*m*-cresol	
Thiodiethylene-bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate).	
2,2'-(2,5-Thiophenediyl) bis[5-*tert*-butylbenzoxazole]	
Thiram	

Substances	Limitations
Thymol	For use as preservative only.
Titanium dioxide	
Titanium dioxide-barium sulfate	
Titanium dioxide-calcium sulfate	
Titanium dioxide-magnesium silicate	
Toluene	
Toluene 2,4-diisocyanate	
Toluene 2,6-diisocyanate	
o- and *p*-Toluene ethyl sulfonamide	
o- and *p*-Toluene sulfonamide	
p-Toluene sulfonic acid	
p- (*p'*-Toluene-sulfonylamide)-diphenylamide	
Triazine-formaldehyde resins as described in § 175.300(b)(3)(xiii).	
Tributoxyethyl phosphate	
Tributylcitrate	
Tri-*tert*-butyl-*p*-phenyl phenol	For use as preservative only.
Tributyl phosphate	
Tributyltin chloride complex of ethylene oxide condensate of dehydroabietylamine.	For use as preservative only.
Tri-*n*-butyltin acetate	For use as preservative only.
Tri-*n*-butyltin neodecanoate	For use as preservative only.
1,1,1-Trichloroethane	
1,1,2-Trichloroethane	
Trichloroethylene	
Tri-β-chloroethyl phosphate	
Tridecyl alcohol	
Triethanolamine	
3-(Triethoxysilyl) propylamine	
Triethylene glycol	
Triethylene glycol dibenzoate	
Triethylene glycol di(2-ethylhexoate)	
Triethylene glycol polyester of benzoic acid and phthalic acid.	
Triethylhexyl phosphate	
Triethylphosphate	
2,4,5-Trihydroxy butyrophenone	
Triisopropanolamine	
Trimethylol propane	
2,2,4-Trimethylpentanediol-1,3-diisobutyrate	
Trimeric aromatic amine resin from diphenylamine and acetone of molecular weight approximately 500.	
Tri(nonylphenyl) phosphite-formaldehyde resins	As identified in § 177.2600(c)(4)(iii) of this chapter. For use only as a stabilizer.
Triphenylphosphate	
Tripropylene glycol monomethyl ether	
1,3,5-Tris (3,5-di-*tert*-butyl-4-hydroxy-benzyl)-*s*-triazine-2,4,6 (1H,3H,5H)-trione.	
Tris (*p*-tertiary butyl phenyl) phosphate	
Tris(2-methyl-4-hydroxy-5-*tert*-butyl-phenyl)butane	
Turpentine	
Urea-formaldehyde resins as described in § 175.300(b)(3)(xii).	
Vegetable oil, sulfonated or sulfated, potassium salt	
Vinyl acetate-maleic anhydride copolymer, sodium salt	
Waxes, petroleum	
Wax, petroleum, chlorinated (40% to 70% chlorine)	
Waxes, synthetic paraffin (Fischer-Tropsch process)	
3-(2-Xenolyl)-1,2-epoxy-propane	
Xylene	
Xylene (or toluese) alkylated with dicyclopentadiene	
Zein	
Zinc acetate	
Zinc ammonium chloride	
Zinc dibenzyl dithiocarbamate	
Zinc dibutyldithiocarbamate	
Zinc diethyldithiocarbamate	
Zinc di(2-ethylhexoate)	
Zinc formaldehyde sulfoxylate	
Zinc naphthenate and dehydroabietylamine mixture	
Zinc nitrate	
Zinc orthophosphate	
Zinc resinate	
Zinc sulfide	
Zineb (zinc ethylenebis-dithiocarbamate)	
Ziram (zinc dimethyldithiocarbamate)	

§ 175.125 Pressure-sensitive adhesives.

Pressure-sensitive adhesives may be safely used as the food-contact surface of labels and/or tapes applied to food, in accordance with the following prescribed conditions:

(a) Pressure-sensitive adhesives prepared from one or a mixture of two or more of the substances listed in this paragraph may be used as the food-contact surface of labels and/or tapes applied to poultry, dry food, and processed, frozen, dried, or partially dehydrated fruits or vegetables.

(1) Substances generally recognized as safe in food.

(2) Substances used in accordance with a prior sanction or approval.

(3) Color additives listed for use in or on food in Part 8 of this chapter.

(4) Substances identified in § 172.615 of this chapter other than substances used in accordance with paragraph (a)(2) of this section.

(5) Polyethylene, oxidized; complying with the identity precribed in § 177.1620(a) of this chapter.

(b) Pressure-sensitive adhesives prepared from one or a mixture of two or more of the substances listed in this paragraph may be used as the food-contact surface of labels and/or tapes applied to raw fruit and raw vegetables.

(1) Substances listed in paragraph (a) (1), (2), (3), and (5) of this section, and those substances prescribed by paragraph (a)(4) of this section that are not identified in paragraph (b)(2) of this section.

(2) Substances identified in this subparagraph and subject to the limitations provided:

BHA.
BHT.
Butadiene-acrylonitrile copolymer.
Butadiene-acrylonitrile-styrene copolymer.
Butadiene-styrene copolymer.
Butyl rubber.
Chlorinated natural rubber.
Isobutylene-styrene copolymer.
Petrolatum.
Polybutene-1.
Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b) of this chapter.
Polyisobutylene.
cis-1,4-Polyisoprene.
Polystyrene.
Propyl gallate.
Rapeseed oil, vulcanized.
Rosins and rosin derivatives as provided in § 178.3870 of this chapter.
Rubber hydrochloride.
Rubber (natural latex solids or crepe, smoked or unsmoked).
Terpene resins (α- and β-pinene), homopolymers, copolymers, and condensates with phenol, formaldehyde, coumarone, and/or indene.
Tetrasodium ethylenediaminetetraacetate.
Tri(mixed mono- and dinonylphenyl) phosphite (which may contain not more than 1 percent by weight of triisopropanolamine).

(c) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

Subpart C—Substances for Use as Components of Coatings

§ 175.210 Acrylate ester copolymer coating.

Acrylate ester copolymer coating may safely be used as a food-contact surface of articles intended for packaging and holding food, including heating of prepared food, subject to the provisions of this section:

(a) The acrylate ester copolymer is a fully polymerized copolymer of ethyl acrylate, methyl methacrylate, and methacrylic acid applied in emulsion form to molded virgin fiber and heat-cured to an insoluble resin.

(b) Optional substances used in the preparation of the polymer and in the preparation and application of the emulsion may include substances named in this paragraph, in an amount not to exceed that required to accomplish the desired technical effect and subject to any limitation prescribed: *Provided, however*, That any substance named in this paragraph and covered by a specific regulation in Subchapter B of this chapter must meet any specifications in such regulation.

List of substances:	Limitations
Aluminum stearate	
Ammonium lauryl sulfate	
Borax	Not to exceed the amount required as a preservative in emulsion defoamer.
Disodium hydrogen phosphate.	Do.
Formaldehyde	
Glyceryl monostearate	
Methyl cellulose	
Mineral oil	
Paraffin wax	
Potassium hydroxide	
Potassium persulfate	
Tallow	
Tetrasodium pyrophosphate	
Titanium dioxide	

(c) The coating in the form in which it contacts food meets the following tests:

(1) An appropriate sample when exposed to distilled water at 212° F for 30 minutes shall yield total chloroform-soluble extractables not to exceed 0.5 milligram per square inch.

(2) An appropriate sample when exposed to *n*-heptane at 120° F for 30 minutes shall yield total chloroform-soluble extractables not to exceed 0.5 milligram per square inch.

§ 175.230 Hot-melt strippable food coatings.

Hot-melt strippable food coatings may be safely applied to food, subject to the provisions of this section.

(a) The coatings are applied to and used as removable coatings for food.

(b) The coatings may be prepared, as mixtures, from the following substances:

(1) Substances generally recognized as safe in food.

(2) Substances identified in this subparagraph.

List of substances:	*Limitations*
Acetylated monoglycerides	Complying with 172.828 of this chapter.
Cellulose acetate butyrate	----------
Cellulose acetate proprionate.	----------
Mineral oil, white	For use only as a component of hot-melt strippable food coatings applied to frozen meats and complying with § 172.878 of this chapter.

§ 175.250 Paraffin (synthetic).

Synthetic paraffin may be safely used as an impregnant in, coating on, or component of coatings on articles used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) The additive is synthesized by the Fischer-Tropsch process from carbon monoxide and hydrogen, which are catalytically converted to a mixture of paraffin hydrocarbons. Lower molecular-weight fractions are removed by distillation. The residue is hydrogenated and further treated by percolation through activated charcoal.

(b) Synthetic paraffin shall conform to the following specifications:

(1) *Congealing point.* The substance has a congealing point of not less than 200° F nor more than 210° F as determined by A.S.T.M. D–938–49.

(2) *Oil content.* The substance has an oil content not exceeding 0.5 percent as determined by A.S.T.M. D–721–56T.

(3) *Absorptivity.* The substance has an absorptivity at 290 millimicrons in decahydronaphthalene at 190° F not exceeding 0.01 as determined by A.S.T.M. 131.

(c) The provisions of this section are not applicable to synthetic paraffin used in food-packaging adhesives complying with § 175.105.

§ 175.260 Partial phosphoric acid esters of polyester resins.

Partial phosphoric acid esters of polyester resins identified in this section and applied on aluminum may be safely used as food-contact coatings, in accordance with the following prescribed conditions:

(a) For the purpose of this section, partial phosphoric acid esters of polyester resins are prepared by the reaction of trimellitic anhydride with 2,2-dimethyl-1,3-propanediol followed by reaction of the resin thus produced with phosphoric acid anhydride to produce a resin having an acid number of 81 to 98 and a phosphorus content of 4.05 to 4.65 percent by weight.

(b) The coating is chemically bonded to the metal and cured at temperatures exceeding 450° F.

(c) The finished food-contact coating, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use, as determined from tables 1 and 2 of § 175.300(d), yields total extractives in each extracting solvent not to exceed 0.3 milligrams per square inch of food-contact surface, as determined by the methods described in § 175.300(e), and the coating yields 2,2-dimethyl-1, 3-propanediol in each extracting solvent not to exceed 0.3 micrograms per square inch of food-contact surface. In testing the finished food-contact articles, a separate test sample is to be used for each required extracting solvent.

§ 175.270 Poly(vinyl fluoride) resins.

Poly(vinyl fluoride) resins identified in this section may be safely used as components of food-contact coatings for containers having a capacity of not less than 5 gallons, subject to the provisions of this section.

(a) For the purpose of this section, poly(vinyl fluoride) resins consist of basic resins produced by the polymerization of vinyl fluoride.

(b) The poly(vinyl fluoride) basic resins have an intrinsic viscosity of not less than 0.75 deciliter per gram as determined by ASTM Method D 1243–66, modified as follows:

(1) Solvent: *N,N*-Dimethylacetamide, technical grade.

(2) Solution: Powdered resin and solvent are heated at 120° C until the resin is dissolved.

(3) Temperature: Flow times of the solvent and solution are determined at 110° C.

(4) Viscometer: Cannon-Ubbelohde size 50 semimicro dilution viscometer (or equivalent).

(5) Calculation: The calculation method used is that described in appendix A1.2.2 (ASTM Method D 1243–66) with the reduced viscosity determined for three concentration levels, not greater than 0.5 gram per deciliter, and extrapolated to zero concentration for intrinsic viscosity. The following formula is used for determining reduced viscosity:

$$\text{Reduced viscosity in terms of deciliters per gram} = \frac{t - to}{to \times c}$$

Where:
t = Solution efflux time.
to = Solvent efflux time.
c = Concentration of solution in terms of grams per deciliter.

§ 175.300 Resinous and polymeric coatings.

Resinous and polymeric coatings may be safely used as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The coating is applied as a continuous film or enamel over a metal substrate, or the coating is intended for repeated food-contact use and is applied to any suitable substrate as a continuous film or enamel that serves as a functional barrier between the food and the substrate. The coating is characterized by one or more of the following descriptions:

(1) Coatings cured by oxidation.

(2) Coatings cured by polymerization, condensation, and/or cross-linking without oxidation.

(3) Coatings prepared from prepolymerized substances.

(b) The coatings are formulated from optional substances that may include:

(1) Substances generally recognized as safe in food.

(2) Substances the use of which is permitted by regulations in this part or which are permitted by prior sanction or approval and employed under the specific conditions, if any, of the prior sanction or approval.

(3) Any substance employed in the production of resinous and polymeric coatings that is the subject of a regulation in Subchapter B of this chapter and conforms with any specification in such regulation. Substances named in this paragraph (b) (3) and further identified as required:

(i) Drying oils, including the triglycerides or fatty acids derived therefrom:

Beechnut.
Candlenut.
Castor (including dehydrated).
Chinawood (tung).
Coconut.
Corn.
Cottonseed.
Fish (refined).
Hempseed.
Linseed.
Oiticica.

Perilla.
Poppyseed.
Pumpkinseed.
Safflower.
Sesame.
Soybean.
Sunflower.
Tall oil.
Walnut.

The oils may be raw, heat-bodied, or blown. They may be refined by filtration, degumming, acid or alkali washing, bleaching, distillation, partial dehydration, partial polymerization, or solvent extraction, or modified by combination with maleic anhydride.

(ii) Reconstituted oils from triglycerides or fatty acids derived from the oils listed in paragraph (b)(3)(i) of this section to form esters with:

Butylene glycol.
Ethylene glycol.
Pentaerythritol.
Polyethylene glycol.
Polypropylene glycol.
Propylene glycol.
Sorbitol.
Trimethylol ethane.
Trimethylol propane.

(iii) Synthetic drying oils, as the basic polymer:

Butadiene and methylstyrene copolymer.
Butadiene and styrene copolymer, blown or unblown.
Maleic anhydride adduct of butadiene styrene.
Polybutadiene.

(iv) Natural fossil resins, as the basic resin:

Copal.
Damar.
Elemi.
Gilsonite.
Glycerol ester of damar, copal, elemi, and sandarac.
Sandarac.
Shellac.
Utah coal resin.

(v) Rosins and rosin derivatives, with or without modification by polymerization, isomerization, incidental decarboxylation, and/or hydrogenation, as follows:

(*a*) Rosins, refined to color grade of K or paler:

Gum rosin.
Tall oil rosin.
Wood rosin.

(*b*) Rosin esters formed by reacting rosin (paragraph (b)(3)(v)(*a*) of this section) with:

4,4'-*sec*-Butylidenediphenol-epichlorohydrin (epoxy).
Diethylene glycol.
Ethylene glycol.
Glycerol.
4,4'-Isopropylidenediphenol-epichlorohydrin (epoxy).
Methyl alcohol.
Pentaerythritol.

(*c*) Rosin esters (paragraph (b)(3)(v)(*b*) of this section) modified by reaction with:

Maleic anhydride.
o-, *m*-, and *p*-substituted phenol-formaldehydes listed in paragraph (b)(3)(vi) of this section.
Phenol-formaldehyde.

(*d*) Rosin salts:

Calcium resinate (limed rosin).
Zinc resinate.

(vi) Phenolic resins as the basic polymer formed by reaction of phenols with formaldehyde:

(*a*) Phenolic resins formed by reaction of formaldehyde with:

Alkylated (methyl, ethyl, propyl, isopropyl, butyl) phenols.
p-*tert*-Amylphenol.
4,4'-*sec*-Butylidenediphenol.
p-*tert*-Butylphenol.
o-, *m*-, and *p*-Cresol.
p-Cyclohexylphenol.
4,4'-Isopropylidenediphenol.
p-Nonylphenol.
p-Octylphenol.
3-Pentadecyl phenol mixture obtained from cashew nut shell liquid.
Phenol.
Phenyl *o*-cresol.
p-Phenylphenol.
Xylenol.

(*b*) Adjunct for phenolic resins: Aluminum butylate.

(vii) Polyester resins (including alkyd-type), as the basic polymers, formed as esters of acids listed in paragraph (b)(3)(vii) (*a*) and (*b*) of this section by reaction with alcohols in paragraph (b)(3)(vii) (*c*) and (*d*) of this section.

(*a*) Polybasic acids:

Adipic.
Dimerized fatty acids derived from oils listed in paragraph (b)(3)(i) of this section.
Diphenolic acid.
Fumaric.
Isophthalic.
Maleic.
Orthophthalic.
Sebacic.
Terephthalic.
Terpene-maleic acid adduct.
Trimellitic.

(*b*) Monobasic acids:

Benzoic acid.
tert-Butyl benzoic acid.
Fatty acids derived from oils listed in paragraph (b)(3)(i) of this section.
Rosins listed in paragraph (b)(3)(v)(*a*) of this section, for use only as reactants in oil-based or fatty acid-based alkyd resins.

(*c*) Polyhydric alcohols:

Butylene glycol.
Diethylene glycol.
2,2-Dimethyl-1,3-propanediol for use only in forming polyester resins for coatings intended for use in contact with non-alcoholic foods.
Ethylene glycol.
Glycerol.
Mannitol.
a-Methyl glucoside.
Pentaerythritol.
Propylene glycol.
Sorbitol.
Trimethylol ethane.
Trimethylol propane.

(*d*) Monohydric alcohols:

Cetyl alcohol.
Decyl alcohol.
Lauryl alcohol.
Myristyl alcohol.
Octyl alcohol.
Stearyl alcohol.

(viii) Epoxy resins, catalysts, and adjuncts:

(*a*) Epoxy resins, as the basic polymer:

(Alkoxy C_{12}-C_{16})-2,3-epoxypropane, in which the alkyl groups are even numbered and consist of a maximum of 1 percent C_{10} carbon atoms and a minimum of 48 percent C_{12} carbon atoms and a minimum of 18 percent C_{14} carbon atoms, for use only in coatings that are intended for contact with dry bulk foods at room temperature.
4,4'-*sec*-Butylidenediphenol-epichlorohydrin.
4,4'-*sec*-Butylidenediphenol- epichlorohydrin reacted with one or more of the drying oils or fatty acids listed in paragraph (b)(3)(i) of this section.
4,4'-*sec*-Betylidenediphonel - epichlorohydrin chemically treated with one or more of the following substances:
Allyl ether of mono-, di-, or trimethylol phenol.
4,4'-*sec*-Butylidenediphenol-formaldehyde.
4,4'-Isopropylidenediphenol-formaldehyde.
Melamine-formaldehyde.
Phenol-formaldehyde.
Urea-formaldehyde.
Epoxidized polybutadiene.
Glycidyl ethers formed by reacting phenol-novolak resins within epichlorohydrin.
4,4'-Isopropylidenediphenol-epichlorohydrin.
4,4'-Isopropylidenediphenol-epichlorohydrin reacted with one or more of the drying oils or fatty acids listed in paragraph (b)(3)(i) of this section.
4,4'-Isopropylidenediphonel - epichlorohydrin chemically treated with one or more of the following substances:
Allyl ether of mono-, di-, or trimethyol phenol.
4,4'-*sec*-Butylidenediphenol-formaldehyde.
4,4'-Isopropylidenediphenol-formaldehyde.
Melamine-formaldehyde.
Phenol-formaldehyde.
Urea-formaldehyde.

(*b*) Catalysts and cross-linking agents for epoxy resins:

Cyanoguanidine.
Dibutyl phthalate, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.
Diethylenetriamine.
Diphenylamine.
Ethylenediamine.
Isophthalyl dihydrazide for use only in coatings subject to the provisions of paragraph (c)(3) or (4) of this section.
4,4'-Methylenedianiline, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.
N-Oleyl-1,3-propanediamine with not more than 10 percent by weight of diethylaminoethanol.
Polyamine produced when 1 mole of the chlorohydrin diether of polyethylene glycol 400 is made to react under dehydrohalogenating conditions with 2 moles of *N*-octadecyltrimethylenediamine for use only in coatings that are subject to the provisions of paragraph (c)(3) or (4) of this section and that contact food at temperatures not to exceed room temperature.
Salicylic acid, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.
Stannous 2-ethylhexanoate for use only as a catalyst at a level not to exceed 1 percent by weight of the resin used in coatings that are intended for contact with food under conditions of use D, E, F, and G described in table 2 of paragraph (d) of this section.

Styrene oxide, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.
Tetraethylenepentamine.
Tetraethylenepentamine reacted with equimolar quantities of fatty acids.
Tri(dimethylaminomethyl) phenol and its salts prepared from the fatty acid moieties of the salts listed in paragraph (b)(3)(xxii)(*b*) of this section, for use only in coatings subject to the provisions of paragraph (c) (3) or (4) of this section.
Triethylenetetramine.
Trimellitic anhydride for use only as a cross-linking agent at a level not to exceed 15 percent by weight of the resin intended for use only in contact with food under conditions of use D, E, F, and G described in table 2 of paragraph (d) of this section.

(c) Adjuncts for epoxy resins:

Aluminum butylate.
Polyamides from dimerized vegetable oils and the amine catalysts listed in paragraph (b)(3)(viii)(*b*) of this section, as the basic polymer.

(ix) Coumarone-indene resin, as the basic polymer.

(x) Petroleum hydrocarbon resin (cyclopentadiene type), as the basic polymer.

(xi) Terpene resins, as the basic polymer, from one or more of the following:

Dipentene.
α-Pinene.
β-Pinene.

(xii) Urea-formaldehyde, as the basic polymer:

Urea-formaldehyde.
Urea-formaldehyde chemically modified with methyl, ethyl, butyl, propyl, isopropyl, or isobutyl alcohol.
Urea-formaldehyde chemically modified with one or more of the amine catalysts listed in paragraph (b)(3)(xiii)(*b*) of this section.

(xiii) Triazine-formaldehyde resins, as the basic polymer:

Benzoguanamine-formaldehyde.
Melamine-formaldehyde.
Melamine-formaldehyde chemically modified with one or more of the following amine catalysts:
  Amine catalysts listed in paragraph (b)(3)(viii)(*b*) of this section.
  Dimethylamine-2-methyl-1-propanol.
  Methylpropanolamine.
  Triethanolamine.
Melamine-formaldehyde chemically modified with methyl, ethyl, propyl, isopropyl, butyl, or isobutyl alcohol.

(xiv) Modifiers (for oils and alkyds, including polyesters), as the basic polymer:

Butyl methacrylate.
Cyclopentadiene.
Methyl, ethyl, butyl, or octyl esters of acrylic acid.
Methyl methacrylate.
Styrene.
Vinyl toluene.

(xv) Vinyl resinous substance, as the basic polymers:

Polyvinyl acetate.
Polyvinyl alcohol.
Polyvinyl butyral.
Polyvinyl chloride.
Polyvinyl formal.
Polyvinylidene chloride.
Polyvinyl pyrrolidone.
Polyvinyl stearate.
Vinyl chloride-acetate-2,3-epoxypropyl methacrylate copolymers containing not more than 10 weight percent of total polymer units derived from 2,3-epoxypropyl methacrylate and not more than 0.1 weight percent of unreacted 2,3-epoxypropyl methacrylate monomer for use in coatings for containers.
Vinyl chloride-acetate, hydroxyl-modified copolymer.
Vinyl chloride-acetate, hydroxyl-modified copolymer, reacted with trimellitic anhydride.
Vinyl chloride copolymerized with acrylamide and ethylene in such a manner that the finished copolymers have a minimum weight average molecular weight of 30,000 and contain not more than 3.5 weight percent of total polymer units derived from acrylamide; the acrylamide portion may or may not be subsequently partially hydrolyzed.
Vinyl chloride copolymerized with one or more of the following substances:
  Acrylonitrile.
  Fumaric acid and/or its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters.
  Maleic acid and/or its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters.
5-Norbornene-2,3-dicarboxylic acid, mono-*n*-butyl ester; for use such that the finished vinyl chloride copolymers contain not more than 4 weight percent of total polymer units derived from this comonomer.
  Vinyl acetate.
  Vinylidene chloride.
Vinyl chloride-vinylidene chloride-2,3-epoxypropyl methacrylate copolymers containing not more than 10 weight percent of total polymer units derived from 2,3-epoxypropyl methacrylate and not more than 0.05 weight percent of unreacted 2,3-epoxypropyl methacrylate monomer based on polymer solids for use only in coatings for containers intended for contact with foods under conditions B, C, D, E, F, G, or H described in Table 2 of paragraph (d) of this section.

(xvi) Cellulosics, as the basic polymer:

Carboxymethylcellulose.
Cellulose acetate.
Cellulose acetate-butyrate.
Cellulose acetate-propionate.
Ethylcellulose.
Ethyl hydroxyethylcellulose.
Hydroxyethylcellulose.
Hydroxypropyl methylcellulose.
Methylcellulose.
Nitrocellulose.

(xvii) Styrene polymers, as the basic polymer:

Polystyrene.
α-Methyl styrene polymer.
Styrene copolymerized with one or more of the following:
  Acrylonitrile.
  α-Methylstyrene.

(xviii) Polyethylene and its copolymers as the basic polymer:

Ethylene-ethyl acrylate copolymer.
Ethylene-isobutyl acrylate copolymers containing no more than 35 weight percent of total polymer units derived from isobutyl acrylate.
Ethylene-vinyl acetate copolymer.
Polyethylene.

(xix) Polypropylene as the basic polymer:

Polypropylene.
Maleic anhydride adduct of polypropylene The polypropylene used in the manufacture of the adduct complies with §177.1520(c), item 1.1; and the adduct has a maximum combined maleic anhydride content of 0.8 percent and a minimum intrinsic viscosity of 0.9, determined at 135° C on a 0.1 percent solution of the modified polypropylene in decahydronaphthalene as determined by a method available on request from the Commissioner of Food and Drugs.

(xx) Acrylics and their copolymers, as the basic polymer:

Acrylamide with ethylacrylate and/or styrene and/or methacrylic acid, subsequently reacted with formaldehyde and butanol.
Acrylic acid and the following esters thereof:
  Ethyl.
  Methyl.
Butyl acrylate-styrene-methacrylic acid-hydroxyethyl methacrylate copolymers containing no more than 20 weight percent of total polymer units derived from methacrylic acid and containing no more than 7 weight percent of total polymer units derived from hydroxyethyl methacrylate; for use only in coatings that are applied by electrodeposition to metal substrates.
Butyl acrylate-styrene-methacrylic acid-hydroxypropyl methacrylate copolymers containing no more than 20 weight percent of total polymer units derived from methacrylic acid and containing no more than 7 weight percent of total polymer units derived from hydroxypropyl methacrylate; for use only in coatings that are applied by electrodeposition to metal substrates and that are intended for contact, under condition of use D, E, F, or G described in table 2 of paragraph (d) of this section, with food containing no more than 8 percent of alcohol.
Ethyl acrylate-styrene-methacrylic acid copolymers for use only as modifiers for epoxy resins listed in paragraph (b)(3)(viii)(*a*) of this section.
Ethyl acrylate-methyl methacrylate-styrene-methacrylic acid copolymers for use only as modifiers for epoxy resins listed in paragraph (b)(3)(viii)(*a*) of this section.
2-Ethylhexyl acrylate-methyl methacrylate-acrylic acid copolymers for use only as modifiers for epoxy resins listed in paragraph (b)(3)(viii) of this section.
Methacrylic acid and the following esters thereof:
  Butyl.
  Ethyl.
  Methyl.
Methacrylic acid or its ethyl and methyl esters copolymerized with one or more of the following:
  Acrylic acid.
  Ethyl acrylate.
  Methyl acrylate.

(xxi) Elastomers, as the basic polymer:

Butadiene-acrylonitrile copolymer.
Butadiene-acrylonitrile-styrene copolymer.
Butadiene-styrene copolymer.
Butyl rubber.
Chlorinated rubber.
2-Chloro-1,3-butadiene (neoprene).
Natural rubber (natural latex or natural latex solids, smoked or unsmoked).
Polyisobutylene.
Rubber hydrochloride.
Styrene-isobutylene copolymer.

(xxii) Driers made by reaction of a metal from paragraph (b)(3)(xxii)(*a*) of this section with acid, to form the salt

listed in paragraph (b)(3)(xxii)(b) of this section:

(a) Metals:

Aluminum.
Calcium.
Cerium.
Cobalt.
Iron.
Lithium.
Magnesium.
Manganese.
Zinc.
Zirconium.

(b) Salts:

Caprate.
Caprylate.
Isodecanoate.
Linoleate.
Naphthenate.
Neodecanoate.
Octoate (2-ethylhexoate).
Oleate.
Palmitate.
Resinate.
Ricinoleate.
Soyate.
Stearate.
Tallate.

(xxiii) Waxes:

Paraffin, Type I.
Paraffin, Type II.
Polyethylene.
Sperm oil.
Spermaceti.

(xxiv) Plasticizers:

Acetyl tributyl citrate.
Acetyl triethyl citrate.
Butyl phthalyl butyl glycolate.
Butyl stearate.
p-tert-Butyl phenyl salicylate.
Dibutyl sebacate.
Diethyl phthalate.
Diisobutyl adipate.
Diisooctyl phthalate.
Epoxidized soybean oil (iodine number maximum 14; oxirane oxygen content 6% minimum), as the basic polymer.
Ethyl phthalyl ethyl glycolate.
2-Ethylhexyl diphenyl phosphate.
di-2-Ethylhexyl phthalate.
Glycerol.
Glyceryl monooleate.
Glyceryl triacetate.
Monoisopropyl citrate.
Propylene glycol.
Sorbitol.
Mono-, di-, and tristearyl citrate.
Triethyl citrate.
Triethylene glycol.
3(2-Xenoxyl)-1,2-epoxypropane.

(xxv) Release agents, as the basic polymer, when applicable:

N,N'-Distearoyl ethylenediamine.
Linoleic acid amide.
Oleic acid amide.
Palmitic acid amide.
Petrolatum.
Polyethylene wax.
Polyoxyethylene glycol monooleate (mol. wt. of the polyoxyethylene glycol moiety greater than 300).
Polytetrafluoroethylene.
Silicones (not less than 300 centistokes viscosity): Dimethylpolysiloxanes and/or methylphenylpolysiloxanes. The methylphenylpolysiloxanes contain not more than 2.0 percent by weight of cyclosiloxanes having up to and including 4 siloxy units.
Silicones (not less than 100 centistokes viscosity): Dimethylpolysiloxanes and/or methylphenylpolysiloxanes limited to use only on metal substrates. The methylphenylpolysiloxanes contain not more than 2.0 percent by weight of cyclosiloxanes having up to and including 4 siloxy units.

(xxvi) Pigments and colorants:

Aluminum.
Aluminum hydrate.
Aluminum and potassium silicate (mica).
Aluminum mono-, di-, tristearate.
Aluminum silicate (China clay).
Barium sulfate.
Bentonite.
Bentonite, modified with dimethyl dioctadecyl ammonium ion.
Burnt umber.
Calcium carbonate.
Calcium silicate.
Calcium sulfate.
Carbon black (channel process).
Cobalt oxide–aluminum oxide.
Diatomaceous earth.
Iron oxides.
Magnesium oxide.
Magnesium silicate (talc).
Phthalocyanine blue (C.I. pigment blue 15, C.I. No. 74160).
Raw sienna.
Silica.
Tartrazine lake (certified FD&C Yellow No. 5 only).
Titanium dioxide.
Titanium dioxide–barium sulfate.
Titanium dioxide–magnesium silicate.
Zinc carbonate.
Zinc oxide.

(xxvii) Surface lubricants:

Cottonseed oil and other edible oils.
Dibutyl sebacate.
Dioctyl sebacate.
Glyceryl monostearate.
Lanolin.
Mineral oil, white.
Palm oil.
Paraffin, Type I.
Paraffin, Type II.
Petrolatum.
Stearic acid.

(xxviii) Silicones and their curing catalysts:

(a) Silicones as the basic polymer:

Siloxane resins originating from methyl hydrogen polysiloxane, dimethyl polysiloxane, and methylphenyl polysiloxane.

(b) Curing (cross-linking) catalysts for silicones (the maximum amount of tin catalyst used shall be that required to effect optimum cure but shall not exceed 1 part of tin per 100 parts of siloxane resins solids):

Dibutyltin dilaurate.
Stannous oleate.
Tetrabutyl titanate.

(xxix) Surface active agents:

Poly [2-(diethylamino) ethyl metharylate] phosphate (minimum intrinsic viscosity in water at 25° C is not less than 9.0 deciliters per gram as determined by ASTM Method D 1243–60), for use only as a suspending agent in the manufacture of vinyl chloride copolymers and limited to use at levels not to exceed 0.1 percent by weight of the copolymers.
Sodium dioctyl sulfosuccinate.
Sodium dodecyl benzenesulfonate.
Sodium lauryl sulfate.

(xxx) Antioxidants:

Butylated hydroxyanisole.
Butylated hydroxytoluene.
Gum guaiac.
Dilauryl thiodipropionate.
Nordihydroguaiaretic acid.
Propyl gallate.
Distearyl thiodipropionate.
Thiodipropionic acid.
2,4,5-Trihydroxybutyrophenone.

(xxxi) Can end cements (sealing compounds used for sealing can ends only): In addition to the substances listed in paragraph (b) of this section and those listed in § 177.1210(b)(5) of this chapter, the following may be used:

Butadiene-styrene-fumaric acid copolymer.
4,4'-Butylidenebis(6-*tert*-butyl-*m*-cresol).
Dibenzamido phenyl disulfide.
Di-β-naphthyl phenylenediamine.
Dipentamethylene thiuram tetrasulfide.
Isobutylene-isoprene-divinylbenzene copolymers for use only at levels not to exceed 15 percent by weight of the dry cement composition.
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt, for use only at levels not to exceed 0.6 percent by weight of the cement solids in can end cements for containers having a capacity of not less than 5 gallons.
Sodium decylbenzene sulfonate.
Sodium nitrite for use only at levels not to exceed 0.3 percent by weight of the cement solids in can end cements for containers having a capacity of not less than 5 gallons.
Sodium pentachlorophenate for use as a preservative at 0.1 percent by weight in can-sealing compounds on containers having a capacity of 5 gallons or more.
Sodium phenylphenate.
Tetrasodium EDTA (tetrasodium ethylenediaminetetraacetate).
Tri (mixed mono- and dinonylphenyl) phosphite
Zinc dibutyldithiocarbamate.

(xxxii) Side seam cements: In addition to the substances listed in paragraph (b)(3)(i) to (xxx), inclusive, of this section, the following may be used

p-tert-Butyl perbenzoate as a catalyst for epoxy resin.
epsilon-Caprolactam-(ethylene-ethyl acrylate) graft polymer.
Dicumyl peroxide for use only as polymerization catalyst.
Diisodecyl phthalate for use only as plasticizer in side seam cements for containers intended for use in contact with food only of the types identified in paragraph (d) of this section, table 1, under categories I, II, and VI.
Ethyl toluene sulfonamide.
Polyamides derived from the following acids and amines:
  Acids:
    Adipic.
    Azelaic.
    Sebacic.
    Vegetable oil acids (with or without dimerization).
  Amines:
    Diethylenetriamine.
    Diphenylamine.
    Ethylenediamine.
    Hexamethylenediamine.
    Tetraethylenepentamine.
    Triethylenetetramine.
Sodium pentachlorophenate for use as a preservative at 0.1 percent by weight in can-sealing compounds on containers having a capacity of 5 gallons or more.
Toluene sulfonamide formaldehyde resin (basic polymer).
Triethylene glycol methacrylate for use only as polymerization cross-linking agent in side seam cements for containers intended

for use in contact with food only of the types identified in paragraph (d) of this section, table 1, under categories I, II, and VI.

Urea.

(xxxiii) Miscellaneous materials:

Ammonium citrate.
Ammonium potassium phosphate.
Calcium acetate.
Calcium ethyl acetoacetate.
Calcium glycerophosphate.
Calcium, sodium, and potassium oleates.
Calcium, sodium, and potassium ricinoleates.
Calcium, sodium, and potassium stearates.
Castor oil, hydrogenated.
Cetyl alcohol.
Cyclohexanone-formaldehyde resin produced when 1 mole of cyclohexanone is made to react with 1.65 moles of formaldehyde such that the finished resin has an average molecular weight of 600–610 as determined by ASTM Method D2503. For use only in contact with nonalcoholic and nonfatty foods under conditions of use E, F, and G, described in table 2 of paragraph (d) of this section.
Decyl alcohol.
Disodium hydrogen phosphate.
Ethyl acetoacetate.
Lauryl alcohol.
Lecithin.
Magnesium, sodium, and potassium citrate.
Magnesium glycerophosphate.
Magnesium stearate.
Mono-, di-, and tricalcium phosphate.
Monodibutylamine pyrophosphate as sequestrant for iron.
Mono-, di-, and trimagnesium phosphate.
Myristyl alcohol.
Octyl alcohol.
Phosphoric acid.
Polybutene, hydrogenated; complying with the identity and limitations prescribed by § 178.3740 of this chapter.
Poly(ethylene oxide).
Sodium pyrophosphate.
Stannous chloride.
Stannous stearate.
Stannous sulfate.
Stearyl alcohol.
Tetrasodium pyrophosphate.
Tridecyl alcohol produced from tetrapropylene by the oxo process, for use only as a processing aid in polyvinyl chloride resins.
Vinyl acetate-dibutyl maleate copolymers produced when vinyl acetate and dibutyl maleate are copolymerized with or without one of the monomers: Acrylic acid or glycidyl methacrylate. For use only in coatings for metal foil used in contact with foods that are dry solids with the surface containing no free fat or oil. The finished copolymers shall contain at least 50 weight-percent of polymer units derived from vinyl acetate and shall contain no more than 5 weight-percent of total polymer units derived from acrylic acid or glycidyl methacrylate.

(xxxiv) Polyamide resins derived from dimerized vegetable oil acids (containing not more than 20 percent of monomer acids) and ethylenediamine, as the basic resin, for use only in coatings that contact food at temperatures not to exceed room temperature.

(xxxv) Polyamide resins having a maximum acid value of 5 and a maximum amine value of 8.5 derived from dimerized vegetable oil acids (containing not more than 10 percent of monomer acids), ethylenediamine, and 4,4-bis (4-hydroxyphenyl) pentanoic acid (in an amount not to exceed 10 percent by weight of said polyamide resins); as the basic resin, for use only in coatings that contact food at temperatures not to exceed room temperature provided that the concentration of the polyamide resins in the finished food-contact coating does not exceed 5 milligrams per square inch of food-contact surface.

(xxxvi) Methacrylonitrile grafted polybutadiene copolymers containing no more than 41 weight percent of total polymer units derived from methacrylonitrile; for use only in coatings that are intended for contact, under conditions of use D, E, F, or G described in Table 2 of paragraph (d) of this section, with food containing no more than 8 percent of alcohol.

(c) The coating in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of its intended use as determined from Tables 1 and 2 of paragraph (d) of this section, shall yield chloroform-soluble extractives, corrected for zinc extractives as zinc, oleate, not to exceed the following:

(1) From a coating intended for or employed as a component of a container not to exceed 1 gallon and intended for one-time use, not to exceed 0.5 milligram per square inch nor to exceed that amount as milligrams per square inch that would equal 0.005 percent of the water capacity of the container, in milligrams, divided by the area of the food-contact surface of the container in square inches. From a fabricated container conforming with the description in this paragraph (c) (1), the extractives shall not exceed 0.5 milligram per square inch of food-contact surface nor exceed 50 parts per million of the water capacity of the container as determined by the methods provided in paragraph (e) of this section.

(2) From a coating intended for or employed as a component of a container having a capacity in excess of 1 gallon and intended for one-time use, not to exceed 1.8 milligrams per square inch nor to exceed that amount as milligrams per square inch that would equal 0.005 percent of the water capacity of the container in milligrams, divided by the area of the food-contact surface of the container in square inches.

(3) From a coating intended for or employed as a component of a container for repeated use, not to exceed 18 milligrams per square inch nor to exceed that amount as milligrams per square inch that would equal 0.005 percent of the water capacity of the container in milligrams, divided by the area of the food-contact surface of the container in square inches.

(4) From coating intended for repeated use, and employed other than as a component of a container, not to exceed 18 milligrams per square inch of coated surface.

(d) Tables:

TABLE 1.—*Types of food*

I.	Nonacid (pH above 5.0), aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
II.	Acidic (pH 5.0 or below), aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
III.	Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low or high fat content.
IV.	Dairy products and modifications:
	A. Water-in-oil emulsion, high or low fat.
	B. Oil-in-water emulsion, high or low fat.
V.	Low moisture fats and oils.
VI.	Beverages:
	A. Containing alcohol.
	B. Nonalcoholic.
VII.	Bakery products.
VIII.	Dry solids (no end test required).

TABLE 2.—*Test procedures for determining the amount of extractives from resinous or polymeric coatings, using solvents simulating types of foods and beverages*

Condition of use	Types of food (see table 1)	Extractant		
		Water (time and temperature)	Heptane [1] [2] (time and temperature)	8 pct alcohol (time and temperature)
A. High temperature heat-sterilized (e.g., over 212° F).	I, IV-B	250° F, 2 hr		
	III, IV-A, VII	do	150° F, 2 hr	
	II	212° F, 30 min		
B. Boiling water sterilized	III, VII	do	120° F, 30 min	
C. Hot filled or pasteurized above 150° F.	II, IV-B	Fill boiling, cool to 100° F.		
	III, IV-A	do	120° F., 15 min	
	V		do	
D. Hot filled or pasteurized below 150° F.	II, IV-B, VI-B	150° F, 2 hr		
	III, IV-A	do	100° F, 30 min	
	V		do	
	VI-A			150° F, 2 hr.
E. Room temperature filled and stored (no thermal treatment in the container).	I, II, IV-B, VI-B	120° F, 24 hr		
	III, IV-A	do	70° F, 30 min	
	V, VII		do	
	VI-A			120° F, 24 hr.
F. Refrigerated storage (no thermal treatment in the container).	I, II, III, IV-A, IV-B, VI-B, VII.	70° F, 48 hr		
	VI-A			70° F, 48 hr.
G. Frozen storage (no thermal treatment in the container).	I, II, III, IV-B, VII	70° F, 24 hr		
H. Frozen storage: Ready-prepared foods intended to be reheated in container at time of use:				
1. Aqueous or oil in water emulsion of high or low fat.	I, II, IV-B	212° F, 30 min		
2. Aqueous, high or low free oil or fat.	III, IV-A, VII	do	120° F, 30 min	

[1] Heptane extractant not to be used on wax-lined containers.
[2] Heptane extractivity results must be divided by a factor of five in arriving at the extractivity for a food product.

(e) *Analytical methods*—(1) *Selection of extractability conditions.* First ascertain the type of food product (Table 1, paragraph (d) of this section) that is being packed commercially in the test container and the normal conditions of thermal treatment used in packaging the type of food involved. Using Table 2 (paragraph (d) of this section), select the food-stimulating solvent or solvents (demineralized distilled water, heptane, and/or 8 percent ethyl alcohol) and the time-temperature exaggerations of the container-use conditions. Aqueous products (types I, II, IV–B, and VI–B) require only a water-extractability test at the temperature and time conditions shown for the most severe "conditions of use." Aqueous products with free oil or fat and water-oil emulsions (types III, IV–A, and VII) will require determinations of both water extractability and heptane extractability. Low-moisture fats and oils (type V with no free water) require only the heptane extractability. Alcoholic beverages (type VI–A) require only the 8 percent alcohol extractant. Having selected the appropriate extractant or extractants simulating various types of foods and beverages and the time-temperature exaggerations over normal use, follow the applicable extraction procedure. Adapt the procedure, when necessary, for containers having a capacity of over 1 gallon.

(2) *Selection of coated-container samples.* For consumer-sized containers up to 1 gallon, quadruplicate samples of representative containers (using for each replicate sample the number of containers nearest to an area of 180 square inches) should be selected from the lot to be examined.

(3) *Cleaning procedure preliminary to determining the amount of extractables from coated containers.* Quadruplicate samples of representative containers should be selected from the lot to be examined and must be carefully rinsed to remove extraneous material prior to the actual extraction procedure. Soda fountain pressure-type hot water rinsing equipment, consisting in its simplest form of a ⅜-inch–¼-inch internal diameter metal tube attached to a hot water line and bent so as to direct a stream of water upward, may be used. Be sure hot water has reached a temperature of 190° F–200° F before starting to rinse the container. Invert the container over the top of the fountain and direct a strong stream of hot water against the bottom and all sides for 1 minute, drain, and allow to dry.

(4) *Exposure conditions*—(i) *Water (250° F for 2 hours), simulating high-temperature heat sterilization.* Fill the container within ¼-inch of the top with a measured volume of demineralized distilled water. Cover the container with clean aluminum foil and place the container on a rack in a pressure cooker. Add a small amount of demineralized distilled water to the pressure cooker, but do not allow the water to touch the bottom of the container. Close the cooker securely and start to heat over a suitable burner. When a steady stream of steam emerges from the vent, close the vent and allow the pressure to rise to 15 pounds per square inch (250° F) and continue to maintain this pressure for 2 hours. Slowly release the pressure, open the pressure cooker when the pressure reads zero, and composite the water of each replicate immediately in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e) (5) of this section.

(ii) *Water (212° F for 30 minutes), simulating boiling water sterilization.* Fill the container within ¼-inch of the top with a measured volume of boiling, demineralized distilled water. Cover the container with clean aluminum foil and place the container on a rack in a pressure cooker in which a small amount of demineralized distilled water is boiling. Do not close the pressure vent, but operate at atmospheric pressure so that there is a continuous escape of a small amount of steam. Continue to heat for 30 minutes, then remove the test container and composite the contents of each replicate immediately in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e) (5) of this section.

(iii) *Water (from boiling to 100° F), simulating hot fill or pasteurization above 150° F.* Fill the container within ¼-inch of the top with a measured volume of boiling, demineralized distilled water. Insert a thermometer in the water and allow the uncovered container to stand in a room at 70° F–85° F. When the temperature reads 100° F, composite the water from each replicate immediately in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e) (5) of this section.

(iv) *Water (150° F for 2 hours), simulating hot fill or pasteurization below 150° F.* Preheat demineralized distilled water to 150° F in a clean Pyrex flask. Fill the container within ¼-inch of the top with a measured volume of the 150° F water and cover with clean aluminum foil. Place the test container in an oven maintained at 150° F. After 2 hours, remove the test container from the oven and immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e) (5) of this section.

(v) *Water (120° F for 24 hours), simulating room temperature filling and storage.* Preheat demineralized distilled water to 120° F in a clean Pyrex flask. Fill the container within ¼-inch of the top with a measured volume of the 120° F water and cover with clean aluminum foil. Place the test container in an incubator or oven maintained at 120° F. After 24 hours, remove the test container from the incubator and immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e) (5) of this section.

(vi) *Water (70° F for 48 hours), simulating refrigerated storage.* Bring demineralized distilled water to 70° F in a clean Pyrex flask. Fill the container within ¼-inch of the top with a measured volume of the 70° F water, and cover with clean aluminum foil. Place the test container in a suitable room maintained at 70° F. After 48 hours, immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e) (5) of this section.

(vii) *Water (70° F for 24 hours), simulating frozen storage.* Bring demineralized distilled water to 70° F in a clean Pyrex flask. Fill the container within ¼-inch of the top with a measured volume of the 70° F water and cover with clean aluminum foil. Place the container in a suitable room maintained at 70° F. After 24 hours, immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e) (5) of this section.

(viii) *Water (212° F for 30 minutes), simulating frozen foods reheated in the container.* Fill the container to within ¼-inch of the top with a measured volume of boiling, demineralized distilled water. Cover the container with clean aluminum foil and place the container on a rack in a pressure cooker in which a small amount of demineralized distilled water is boiling. Do not close the pressure vent, but operate at atmospheric pressure so that there is a continuous escape of a small amount of steam. Continue to heat for 30 minutes, then remove the test container and composite the contents of each replicate immediately in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e) (5) of this section.

(ix) *Heptane (150° F for 2 hours) simulating high-temperature heat sterilization for fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208° F) carefully in a clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 150° F. At the same time preheat a pressure cooker or equivalent to 150° F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a measured volume of the 150° F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 150° F incubator. After 2 hours, remove the pressure cooker from the incubator, open the assembly, and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e) (5) of this section.

(x) *Heptane (120° F for 30 minutes), simulating boiling water sterilization of fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208° F) carefully in a clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 120° F. At the same time, preheat a pressure cooker or equivalent to 120° F in an incubator. This pressure cooker is to serve only as a vented container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a measured volume of the 120° F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 120° F incubator. After 30 minutes, remove the pressure cooker from the incubator, open the assembly, and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xi) *Heptane (120° F for 15 minutes), simulating hot fill or pasteurization above 150° F for fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208° F) carefully in a clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 120° F. At the same time, preheat a pressure cooker or equivalent to 120° F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a measured volume of the 120° F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 120° F incubator. After 15 minutes, remove the pressure cooker from the incubator, open the assembly, and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xii) *Heptane (100° F for 30 minutes), simulating hot fill or pasteurization below 150° F for fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208° F) carefully in a clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 100° F. At the same time, preheat a pressure cooker or equivalent to 100° F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a measured volume of the 100° F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 100° F incubator. After 30 minutes, remove the pressure cooker from the incubator, open the assembly and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xiii) *Heptane (70° F for 30 minutes), simulating room temperature filling and storage of fatty foods only.* Fill the test container within ¼-inch of the top with a measured volume of the 70° F heptane and cover with clean aluminum foil. Place the test container in a suitable room maintained at 70° F. After 30 minutes, composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xiv) *Heptane (120° F for 30 minutes), simulating frozen fatty foods reheated in the container.* Preheat redistilled reagent-grade heptane (boiling point 208° F) carefully in a clean Pyrex flask on a water bath or hot plate in a well-ventilated hood to 120° F. At the same time, preheat a pressure cooker to 120° F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within ¼-inch of the top with a measured volume of the 120° F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 120° F incubator. After 30 minutes, remove the pressure cooker from the incubator, open the assembly and immediately composite the heptane from each replicate into a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xv) *Alcohol—8 percent (150° F for 2 hours), simulating alcoholic beverages hot filled or pasteurized below 150° F.* Preheat 8 percent (by volume) ethyl alcohol in demineralized distilled water to 150° F in a clean Pyrex flask. Fill the test container with within ¼-inch of the top with a measured volume of the 8 percent alcohol. Cover the container with clean aluminum foil and place in an oven maintained at 150° F. After 2 hours, remove the container from the oven and immediately composite the alcohol from each replicate in a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xvi) *Alcohol—8 percent (120° F for 24 hours), simulating alcoholic beverages room-temperature filled and stored.* Preheat 8 percent (by volume) ethyl alcohol in demineralized distilled water to 120° F in a clean Pyrex flask. Fill the test container within ¼-inch of the top with a measured volume of the 8 percent alcohol, cover the container with clean aluminum foil and place in an oven or incubator maintained at 120° F. After 24 hours, remove the container from the oven or incubator and immediately composite the alcohol from each replicate into a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xvii) *Alcohol—8 percent (70° F for 48 hours), simulating alcoholic beverages in refrigerated storage.* Bring 8 percent (by volume) ethyl alcohol in demineralized distilled water to 70° F in a clean Pyrex flask. Fill the test container within ¼-inch of the top with a measured volume of the 8 percent alcohol. Cover the container with clean aluminum foil. Place the test container in a suitable room maintained at 70° F. After 48 hours, immediately composite the alcohol from each replicate into a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

NOTE: The tests specified in paragraph (e)(4)(i) through (xvii) of this section are applicable to flexible packages consisting of coated metal contacting food, in which case the closure end is double-folded and clamped with metal spring clips by which the package can be suspended.

(5) *Determination of amount of extractives.*—(i) *Total residues.* Evaporate the food-simulating solvents from paragraph (e)(4)(i) to (xvii), inclusive, of this section to about 100 milliliters in the Pyrex flask and transfer to a clean, tared platinum dish, washing the flask three times with the solvent used in the extraction procedure, and evaporate to a few milliliters on a nonsparking low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at a temperature of 212° F. Cool the platinum dish in a desiccator for 30 minutes and weigh the residue to the nearest 0.1 milligram (*e*). Calculate the extractives in milligrams per square inch and in parts per million for the particular size of container being tested and for the specific food-simulating solvent used.

(*a*) *Water and 8-percent alcohol.*

$$\text{Milligrams extractives per square inch} = \frac{e}{s}$$

$$\text{Extractives residue} = Ex = \frac{(e)(a)(1000)}{(c)(s)}$$

(*b*) *Heptane:*

$$\text{Milligrams extractives per square inch} = \frac{e}{(s)(F)}$$

$$\text{Extractives residue} = Ex = \frac{(e)(a)(1000)}{(c)(s)(F)}$$

Where:

Ex = Extractives residue in ppm for any container size.
e = Milligrams extractives per sample tested.
a = Total coated area, including closure in square inches.
c = Water capacity of container, in grams.
s = Surface of coated area tested, in square inches.
F = Five, the ratio of the amount of extractives removed from a coated container by heptane under exaggerated time-temperature test conditions compared to the amount extracted by a fat or oil from a container tested under exaggerated conditions of thermal sterilization and use.
e' = Chloroform-soluble extractives residue.
ee' = Zinc corrected chloroform-soluble extractive residue.
e' or *ee'* is substituted for *e* in the above equations when necessary.

If when calculated by the equations in paragraph (e)(5)(i)(*a*) and (*b*) of this section, the concentration of extractives residue (*Ex*) exceeds 50 parts per million or the extractives in milligrams per square inch exceed the limitations prescribed in paragraph (c) of this section for the particular container size, proceed to paragraph (e)(2)(ii) of this section (method for determining the amount of chloroform-soluble extractives residue).

(ii) *Chloroform-soluble extractives residue.* Add 50 milliliters of chloroform (freshly distilled reagent grade or a grade having an established consistently low blank) to the dried and weighed residue, (*e*), in the platinum dish, obtained in paragraph (e)(5)(i) of this section. Warm carefully, and filter through Whatman No. 41 filter paper in a Pyrex funnel, collecting the filtrate in a clean, tared platinum dish. Repeat the chloroform extraction, washing the filter paper with this second portion of chloroform. Add this filtrate to the original filtrate and evaporate the total down to a few milliliters on a low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at 212° F. Cool the platinum dish in a desiccator for 30 minutes and weigh to the nearest 0.1 milligram to get the chloroform-soluble extractives residue (*e'*). This *e'* is substituted for *e* in the equations in paragraph (e)(5)(i) (*a*) and (*b*) of this section. If the concentration of extractives (*Ex*) still exceeds 50 parts per million or the extractives in milligrams per square inch exceed the limitations prescribed in paragraph (c) of this section for the particular container size, proceed as follows to correct for zinc extractives ("C" enamels only): Ash the residue in the platinum dish by heating gently over a Meeker-type burner to destroy organic matter and hold at red heat for about 1 minute. Cool in the air for 3 minutes, and place the platinum dish in the desiccator for 30 minutes and weigh to the nearest 0.1 milligram. Analyze this ash for zinc by standard Association of Official Agricultural Chemists methods or equivalent. Calculate the zinc in the ash as zinc oleate, and subtract from the weight of chloroform-soluble extractives residue (*e'*) to obtain the zinc-corrected chloroform-soluble extractives residue (*ee'*). This *ee'* is substituted for *e* in the formulas in paragraph (e)(5)(i) (*a*) and (*b*) of this section. To comply with the limitations in paragraph (c) of this section, the chloroform-soluble extractives residue (but after correction for the zinc extractives in case of "C" enamels) must not exceed 50 parts per million and must not exceed in milligrams per square inch the limitations for the particular article as prescribed in paragraph (c) of this section.

(f) *Equipment and reagent requirements*—(1) *Equipment.*

Rinsing equipment, soda fountain pressure-type hot water, consisting in simplest form of a ⅛-inch–¼-inch inside diameter metal tube attached to a hot water line delivering 190° F–200° F water and bent so as to direct a stream of water upward.

Pressure cooker, 21-quart capacity with pressure gage, safety release, and removable rack, 12.5 inches inside diameter x 11 inches inside height, 20 pounds per square inch safe operating pressure.

Oven, mechanical convection, range to include 120° F–212° F explosion-proof, inside dimensions (minimum), 19" x 19" x 19", constant temperature to ±2° F (water bath may be substituted).

Incubator, inside dimensions (minimum) 19" x 19" x 19" for use at 100° F±2° F explosion proof (water bath may be substituted).

Constant-temperature room or chamber 70° F±2° F minimum inside dimensions 19" x 19" x 19".

Hot plate, nonsparking (explosion proof), top 12" x 20", 2,500 watts, with temperature control.

Platinum dish, 100-milliliter capacity minimum.

All glass, Pyrex or equivalent.

(2) *Reagents.*

Water, all water used in extraction procedure should be freshly demineralized (deionized) distilled water.

Heptane, reagent grade, freshly redistilled before use, using only material boiling at 208° F.

Alcohol, 8 percent (by volume), prepared from undenatured 95 percent ethyl alcohol diluted with demineralized or distilled water.

Chloroform, reagent grade, freshly redistilled before use, or a grade having an established, consistently low blank.

Filter paper, Whatman No. 41 or equivalent.

(g) In accordance with good manufacturing practice, finished coatings intended for repeated food-contact use shall be thoroughly cleansed prior to their first use in contact with food.

(h) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

§ 175.320 Resinous and polymeric coatings for polyolefin films.

Resinous and polymeric coatings may be safely used as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The coating is applied as a continuous film over one or both sides of a base film produced from one or more of the basic olefin polymers complying with § 177.1520 of this chapter. The base polyolefin film may contain optional adjuvant substances permitted for use in polyolefin film by applicable regulations in Parts 170 through 189 of this chapter.

(b) The coatings are formulated from optional substances which are:

(1) Substances generally recognized as safe for use in or on food.

(2) Substances the use of which is permitted under applicable regulations in this part, by prior sanctions, or approvals.

(3) Substances identified in this subparagraph (a)(3) and subject to such limitations as are provided:

List of substances	*Limitations*
(i) Resins and polymers:	
Acrylic acid polymer and its ethyl or methyl esters.	
Acrylamide copolymerized with ethyl acrylate and/or styrene and/or methacrylic acid, and the copolymer subsequently reacted with formaldehyde and butanol.	
Butadiene-acrylonitrile copolymer	
Butadiene-acrylonitrile-styrene terpolymer	
Butyl rubber	
N,N'-Diphenyl-*p*-phenylenediamine	For use only as a polymerization inhibitor in 2-sulfoethyl methacrylate, sodium salt.
2-Ethylhexyl acrylate copolymerized with one or more of the following:	
Acrylonitrile	
Itaconic acid	
Methacrylonitrile	
Methyl acrylate	
Methyl methacrylate	
4,4'-Isopropylidenediphenolepichlorohydrin, average molecular weight 900.	
Melamine-formaldehyde as the basic polymer or chemically modified with methyl alcohol.	
Methacrylic acid and its ethyl or methyl esters copolymerized with one or more of the following:	
Acrylic acid	
Ethyl acrylate	
Methyl acrylate	
α-Methyl styrene polymer	
α-Methylstyrene-vinyltoluene copolymer resins (molar ratio 1 α-methylstyrene to 3 vinyltoluene).	For use only in coatings that contact food under conditions of use D, E, F, or G described in table 2 of § 176.170(c) of this chapter, provided that the concentration of α-methylstyrene-vinyltoluene copolymer resins in the finished food-contact coating does not exceed 1.0 milligram per square inch of food-contact surface.
Petroleum alicyclic hydrocarbon resins	As defined in § 176.170 of this chapter. Blended with butyl rubber for use as a component of coatings on polyolefin fabric for bulk packaging of raw fruits and vegetables and used at a level not to exceed 30 percent by weight of the total coating solids.
Polyamide resins, derived from dimerized vegetable oil acids (containing not more than 20% of monomer acids) and ethylenediamine, as the basic resin.	For use only in coatings for polyolefin films that contact food at temperatures not to exceed room temperature.
Polyamide resins having a maximum acid value of 5 and a maximum amine value of 8.5 derived from dimerized vegetable oil acids (containing not more than 10 percent of monomer acids), ethylenediamine, and 4,4-bis (4-hydroxyphenyl) pentanoic acids (in an amount not to exceed 10 percent by weight of said polyamide resins); as the basic resin.	For use only in coatings that contact food at temperatures not to exceed room temperature provided that the concentration of the polyamide resins in the finished food-contact coating does not exceed 5 milligrams per square inch of food-contact surface.

Substances	*Limitations*
(1) Resins and polymers—continued	
Polyester resins formed by reaction of one or more of the following polybasic acids and monobasic acids with one or more of the following polyhydric alcohols:	
Polybasic acids:	
Adipic	
Azelaic	For use in forming polyester resins intended for use in coatings that contact food only of the type identified in § 176.170 (c) of this chapter, table 1, under category VIII, and under conditions of use E, F, or G, described in table 2 of § 176.170 (c) of this chapter.
Dimerized fatty acids derived from:	
Animal, marine or vegetable fats and oils.	
Tall oil	
Fumaric	
Isophthalic	
Maleic	
o-Phthalic	
Sebacic	
Terephthalic	
Trimellitic	
Monobasic acids:	
Fatty acids derived from:	
Animal, marine, or vegetable fats and oils.	
Gum resin	As defined in § 178.3870 of this chapter. For use in forming polyester resins intended for use in coatings that contact food only of the type identified in § 176.170(c) of this chapter, table 1, under category VIII, and under conditions of use E, F, or G described in table 2 of § 176.170(c) of this chapter.
Tall oil	
Polyhydric alcohols:	
1,3-Butylene cylcol	
Diethylene glycol	
2,2-Dimethyl-1,3-propanediol	
Dipropylene glycol	
Ethylene glycol	
Glycerol	
Mannitol	
α-Methyl glucoside	
Pentaerythritol	
Propylene glycol	
Sorbitol	
Trimethylol ethane	
Trimethylol propane	
Polyethylenimine	**For use only as a primer** subcoat to anchor epoxy surface coatings to the base sheet.
Polystyrene	
Polyvinyl acetate	
Polyvinyl chloride	
Styrene copolymerized with one or more of the following:	
Acrylonitrile	
α-Methyl styrene	
Styrene-isobutylene copolymer	
Terpene resins consisting of polymers of α-pinene, β-pinene, and/or dipentene; acid value less than 5, saponification number less than 5, and color less than 4 on the Gardner scale as measured in 50 percent mineral spirits solution.	
2-Sulfoethyl metacrylate, sodium salt [C.A. Registry No. 10595-80-9].	For use only in copolymer coatings under conditions of use E, F, and G described in table 2 of § 176.170(c) of this chapter and limited to use at a level not to exceed 1.0 percent by weight of the dry copolymer coating.
Vinyl chloride-acetate, hydroxyl-modified copolymer or maleic acid-modified copolymer.	
Vinyl chloride copolymerized with one or more of the following:	
Acrylonitrile	
Vinyl acetate	
Vinylidene chloride	
Vinylidene chloride copolymerized with one or more of the following:	
Acrylic acid and its methyl, ethyl, propyl, butyl, or octyl esters.	
Acrylonitrile.	
Itaconic acid.	
Methacrylic acid and its methyl, ethyl, propyl, butyl, or octyl esters.	
Methacrylonitrile.	
Vinyl chloride.	
(2) Plasticizers:	
Acetyl tributyl citrate	
Acetyl triethyl citrate	
Butyl phthalyl butyl glycolate	
Butyl stearate	
Dibutyl sebacate	
Diethyl phthalate	
2-Ethylhexyl diphenyl phosphate	
Ethyl phthalyl ethyl glycolate	
Glycerol monooleate	
Glycerol triacetate	
Triethyl citrate	

Substances	Limitations
(iii) Adjuvants (release agents, waxes, and dispersants):	
Acetone	
Amides (unsubstituted) of fatty acids from vegetable or animal oils.	
n-Butyl acetate	
n-Butyl alcohol	
Candelilla wax	
Carnauba wax	
Ethyl acetate	
Fatty acids from vegetable or animal oils and their aluminum, ammonium, calcium, magnesium, and sodium salts.	
Hexane	
Methyl ethyl ketone	
Petroleum waxes conforming to specifications included in a regulation in Subchapter B of this chapter.	
Polyvinyl alcohol, minimum viscosity of 4% aqueous solution at 20°C of 4 centipoises and percent alcoholysis of 87–100.	For use only as a dispersing agent at levels not to exceed 6% of total coating weight in coatings for polyolefin films provided the finished polyolefin films contact food only of the types identified in § 176.170(c) of this chapter, table 1, under types V, VIII, and IX.
Sodium dioctyl sulfosuccinate	
Sodium dodecylbenzenesulfonate	
Sodium lauryl sulfate	
Sorbitan and sorbitol esters of fatty acids from vegetable or animal oils.	
Spermaceti wax	
Tetrahydrofuran	
Toluene	

(c) The coating in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of § 176.170(c) of this chapter, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of coated surface.

(d) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

§ 175.350 Vinyl acetate/crotonic acid copolymer.

A copolymer of vinyl acetate and crotonic acid may be safely used as a coating or as a component of a coating which is the food-contact surface of polyolefin films intended for packaging food, subject to the provisions of this section.

(a) The copolymer may contain added optional substances to impart desired properties.

(b) The quantity of any optional substance does not exceed the amount reasonably required to accomplish the intended physical or technical effect nor any limitations further provided.

(c) Any optional substance that is the subject of a regulation in Parts 174, 175, 176, 177, 178, and § 179.45 of this chapter conforms with any specifications in such regulation.

(d) Optional substances as provided in paragraph (a) of this section include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for uses with a copolymer of vinyl acetate and crotonic acid and used in accordance with such sanction or approval.

(3) Substances identified in this subparagraph and subject to such limitations as are provided:

List of substances	Limitations
Silica	
Japan wax	

(e) Copolymer of vinyl acetate and crotonic acid used as a coating or as a component of a coating conforming with the specifications of paragraph (e)(1) of this section are used as provided in paragraph (e)(2) of this section.

(1) *Specifications.* (i) The chloroform-soluble portion of the water extractives of the coated film obtained with distilled water at 120° F for 24 hours does not exceed 0.5 milligram per square inch of coated surface.

(ii) The chloroform-soluble portion of the *n*-heptane extractives of the coated film obtained with *n*-heptane at 70° F for 30 minutes does not exceed 0.5 milligram per square inch of coated surface.

(2) *Conditions of use.* The copolymer of vinyl acetate and crotonic acid is used as a coating or as a component of a coating for polyolefin films for packaging bakery products and confectionery.

§ 175.360 Vinylidene chloride copolymer coatings for nylon film.

Vinylidene chloride copolymer coatings identified in this section and applied on nylon film may be safely used as food-contact surfaces, in accordance with the following prescribed conditions:

(a) The coating is applied as a continuous film over one or both sides of a base film produced from nylon resins complying with § 177.1500 of this chapter.

(b) The coatings are prepared from vinylidene chloride copolymers produced by copolymerizing vinylidene chloride with one or more of the monomers acrylic acid, acrylonitrile, ethyl acrylate, methacrylic acid, and methyl acrylate. The finished copolymers contain at least 50 weight percent of polymer units derived from vinylidene chloride.

(c) Optional adjuvant substances employed in the production of the coatings or added thereto to impart desired properties may include sodium dodecylbenzenesulfonate.

(d) The coating in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of § 176.170(c) of this chapter, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of coated surface when tested by the methods described in § 176.170(d) of this chapter.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

§ 175.365 Vinylidene chloride copolymer coatings for polycarbonate film.

Vinylidene chloride copolymer coatings identified in this section and applied on polycarbonate film may be safely used as food-contact surfaces, in accordance with the following prescribed conditions:

(a) The coating is applied as a continuous film over one or both sides of a base film produced from polycarbonate resins complying with § 177.1580 of this chapter.

(b) The coatings are prepared from vinylidene chloride copolymers produced by copolymerizing vinylidene chloride with acrylonitrile, methyl acrylate, and acrylic acid. The finished copolymers contain at least 50 weight-percent of polymer units derived from vinyldene chloride.

(c) Optional adjuvant substances employed in the production of the coatings or added thereto to impart desired properties may include sodium dodecylbenzenesulfonate in addition to substances described in § 174.1(d) of this chapter.

(d) The coating in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of § 176.170(c) of this chapter, shall yield net chloroform-soluble extractives in each extracting solvent not to exceed 0.5 milligram per square inch of coated surface as determined by the methods described in § 176.170(d) of this chapter. In testing the finished food-contact articles, a separate test sample is to be used for each required extracting solvent.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

§ 175.380 Xylene-formaldehyde resins condensed with 4,4′-isopropylidenediphenol-epichlorohydrin epoxy resins.

The resins identified in paragraph (a) of this section may be safely used as a food-contact coating for articles intended for use in contact with food, in accordance with the following prescribed conditions.

(a) The resins are produced by the condensation of xylene-formaldehyde resin and 4,4′-isopropylidenediphenol-epichlorohydrin epoxy resins, to which may have been added certain optional adjuvant substances required in the production of the resins or added to impart desired physical and technical properties. The optional adjuvant substances may include resins

produced by the condensation of allyl ether of mono-, di-, or trimethylol phenol and capryl alcohol and also may include substances identified in § 175.300(b)(3), with the exception of paragraph (b)(3)(xxxi) and (xxxii) of that section.

(b) The resins identified in paragraph (a) of this section may be used as a food-contact coating for articles intended for contact at temperatures not to exceed 160° F with food of types I, II, VI–A and B, and VIII described in table 1 of § 176.170(c) of this chapter provided that the coating in the finished form in which it is to contact food meets the following extractives limitations when tested by the methods provided in § 175.300(e):

(1) The coating when extracted with distilled water at 180° F for 24 hours yields total extractives not to exceed 0.05 milligram per square inch of food-contact surface.

(2) The coating when extracted with 8 percent (by volume) ethyl alcohol in distilled water at 160° F for 4 hours yields total extractives not to exceed 0.05 milligram per square inch of food-contact surface.

(c) The resins identified in paragraph (a) of this section may be used as a food-contact coating for articles intended for contact at temperatures not to exceed room temperature with food of type VI–C described in table 1 of § 176.170(c) of this chapter provided the coating in the finished form in which it is to contact food meets the following extractives limitations when tested by the methods provided in § 175.300(e):

(1) The coating when extracted with distilled water at 180° F for 24 hours yields total extractives not to exceed 0.05 milligram per square inch of food-contact surface.

(2) The coating when extracted with 50 percent (by volume) ethyl alcohol in distilled water at 180° F for 24 hours yields total extractives not to exceed 0.05 milligram per square inch.

§ 175.390 Zinc-silicon dioxide matrix coatings.

Zinc-silicon dioxide matrix coatings may be safely used as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section;

(a) The coating is applied to a metal surface, cured, and washed with water to remove soluble substances.

(b) The coatings are formulated from optional substances which include:

(1) Substances generally recognized as safe.

(2) Substances for which safe conditions of use have been prescribed in § 175.300.

(3) Substances identified in paragraph (c) of this section, subject to the limitations prescribed.

(c) The optional substances permitted are as follows:

Lists of substances	*Limitations*
Ethylene glycol	As a solvent removed by water washing
Iron oxide	
Lithium hydroxide	Removed by water washing.
Methyl orange	As an acid-base indicator.
Potassium dichromate	Removed by water washing.
Silica gel	
Sodium silicate	
Zinc, as particulate metal	

(d) The coating in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under the conditions of its intended use as shown in Tables 1 and 2 of § 175.300(d) (using 20 percent alcohol as the solvent when the type of food contains approximately 20 percent alcohol) shall yield total extractives not to exceed those prescribed in § 175.300(c)(3); lithium extractives not to exceed 0.025 milligram per square inch of surface; and chromium extractives not to exceed 0.05 microgram per square inch of surface.

(e) The coatings are used as food-contact surfaces for bulk reusable containers intended for storing, handling, and transporting food.

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

Subpart A—[Reserved]

Subpart B—Substances for Use Only as Components of Paper and Paperboard

Sec.

176.110 Acrylamide-acrylic acid resins.
176.120 Alkyl ketene dimers.
176.130 Anti-offset substances.
176.150 Chelating agents used in the manufacture of paper and paperboard.
176.160 Chromium (Cr III) complex of *N*-ethyl - *N*-heptadecylfluoro-octane sulfonyl glycine.
176.170 Components of paper and paperboard in contact with aqueous and fatty foods.
176.180 Components of paper and paperboard in contact with dry food.
176.200 Defoaming agents used in coatings.
176.210 Defoaming agents used in the manufacture of paper and paperboard.
176.230 3,5 - Dimethyl - 1,3,5,2*H* - tetrahydrothiadiazine-2-thione.
176.250 Poly - 1,4,7,10,13 - pentaaza - 15 - hydroxyhexadecane.
176.260 Pulp from reclaimed fiber.
176.300 Slimicides.
176.320 Sodium nitrate-urea complex.
176.350 Tamarind seed kernel powder.

AUTHORITY: Secs. 409, 701, 52 Stat. 1055–1056 as amended, 72 Stat. 1785–1788 as amended (21 U.S.C. 348, 371), unless otherwise noted.

Subpart A—[Reserved]

Subpart B—Substances for Use Only as Components of Paper and Paperboard

§ 176.110 Acrylamide-acrylic acid resins.

Acrylamide-acrylic acid resins may be safely used as components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) Acrylamide-acrylic acid resins are produced by the polymerization of acrylamide with partial hydrolysis or by the copolymerization of acrylamide and acrylic acid.

(b) The acrylamide-acrylic acid resins contain less than 0.2 percent residual monomer.

(c) The resins are used as adjuvants in the manufacture of paper and paperboard in amounts not to exceed that necessary to accomplish the technical effect and not to exceed 2 percent by weight of the paper or paperboard.

§ 176.120 Alkyl ketene dimers.

Alkyl ketene dimers may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The alkyl ketene dimers are manufactured by the dehydrohalogenation of the acyl halides derived from the fatty acids of animal or vegetable fats and oils.

(b) The alkyl ketene dimers are used as an adjuvant in the manufacture of paper and paperboard under such conditions that the alkyl ketene dimers and their hydrolysis products dialkyl ketones do not exceed 0.4 percent by weight of the paper or paperboard.

(c) The alkyl ketene dimers may be used in the form of an aqueous emulsion which may contain sodium lignosulfonate as a dispersant.

§ 176.130 Anti-offset substances.

Substances named in paragraphs (b) and (c) of this section may be safely used to prevent the transfer of inks employed in printing and decorating paper and paperboard used for food packaging in accordance with the provisions of this section:

(a) The substances are applied to the nonfood contact, printed side of the paper or paperboard in an amount not greater than that required to accomplish the technical effect nor greater than any specific limitations, where such are provided.

(b) Anti-offset powders are prepared from substances that are generally recognized as safe in food, substances for which prior sanctions or approvals were granted and which are used in accordance with the specific provisions of such sanction or approval, and substances named in paragraph (c) of this section.

(c) The substances permitted are as follows:

Substances	*Limitations*
Carbon tetrachloride	
Methyl hydrogen polysiloxanes	
Industrial starch—modified	Complying with § 178.3520 of this chapter.
Stannous oleate	
Zinc-2-ethyl hexoate	

§ 176.150 Chelating agents used in the manufacture of paper and paperboard.

The substances named in paragraph (a) of this section may be safely used in the manufacture of paper and paperboard, in accordance with the conditions prescribed in paragraphs (b) and (c) of this section:

(a) Chelating agents:

List of substances:	*Limitations*
Ammonium fructoheptonate	
Ammonium glucoheptonate	
Disodium ethylenediamine tetraacetate	
Pentasodium salt of diethylenetriamine pentaacetate	
Sodium fructoheptonate	
Sodium glucoheptonate	
Tetrasodium ethylenediamine tetraacetate	
Trisodium *N*-hydroxyethyl ethylenediamine triacetate	

(b) Any one or any combination of the substances named is used or intended for use as chelating agents.

(c) The substances are added in an amount not greater than that required to accomplish the intended technical effect nor greater than any specific limitation, where such is provided.

§ 176.160 Chromium (Cr III) complex of *N*-ethyl-*N*-heptadecylfluoro-octane sulfonyl glycine.

The chromium (Cr III) complex of *N*-ethyl-*N*-heptadecylfluoro-octane sulfonyl glycine containing up to 20 percent by weight of the chromium (Cr III) complex of heptadecylfluoro-octane sulfonic acid may be safely used as a component of paper for packaging dry food when used in accordance with the following prescribed conditions.

(a) The food additive is used as a component of paper in an amount not to exceed 0.5 percent by weight of the paper.

(b) (1) The food-contact surface of the paper is overcoated with a polymeric or resinous coating at least ⅓-mil in thickness, that meets the provision of § 176.170; or

(2) The treated paper forms one or more plies of a paper in a multiwall bag and is separated from the food by at least one ply of packaging films or grease-resistant papers which serves as a functional barrier between the food additive and the food. Such packaging films or grease-resistant papers conform with appropriate food additive regulations.

(c) The labeling of the food additive shall contain adequate directions for its use to insure compliance with the requirements of paragraphs (a) and (b) of this section.

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

Substances identified in this section may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packaging, processing, preparing, treating, packaging, transporting, or holding aqueous and fatty foods, subject to the provisions of this section. Components of paper and paperboard in contact with dry food of the type identified under type VIII of table 1 in paragraph (c) of this section are subject to the provisions of § 176.180.

(a) Substances identified in paragraph (a) (1) through (5) of this section may be used as components of the food-contact surface of paper and paperboard. Paper and paperboard products shall be exempted from compliance with the extractives limitations prescribed in paragraph (c) of this section: *Provided*, That the components of the food-contact surface consist entirely of one or more of the substances identified in this paragraph: *And provided further*, That if the paper or paperboard when extracted under the conditions prescribed in paragraph (c) of this section exceeds the limitations on extractives contained in paragraph (c) of this section, information shall be available from manufacturing records from which it is possible to determine that only substances identified in this paragraph (a) are present in the food-contact surface of such paper or paperboard.

(1) Substances generally recognized as safe in food.

(2) Substances generally recognized as safe for their intended use in paper and paperboard products used in food packaging.

(3) Substances used in accordance with a prior sanction or approval.

(4) Substances that by regulation in Parts 170 through 189 of this chapter may be safely used without extractives limitations as components of the uncoated or coated food-contact surface of paper and paperboard in contact with aqueous or fatty food, subject to the provisions of such regulation.

(5) Substances identified in this subparagraph, as follows:

List of substances	*Limitations*
Acetyl peroxide	For use only as polymerization catalyst.
Acrylamide-methacrylic acid-maleic anhydride copolymers containing not more than 0.2 percent of residual acrylamide monomer and having an average nitrogen content of 14.9 percent such that a 1 percent by weight aqueous solution has a minimum viscosity of 600 centipoises at 75° F, as determined by LVG-series Brookfield viscometer (or equivalent) using a No. 2 spindle at 30 r.p.m.	For use only as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard in such an amount that the finished paper and paperboard will contain the additive at a level not in excess of 0.05 percent by weight of dry fibers in the finished paper and paperboard.
Acrylamide-β-methacrylyloxy ethyltrimethylammonium methyl sulfate copolymer resins containing not more that 10 molar percent of β-methacrylyloxyethyltrimethylammonium methyl sulfate and containing less than 0.2% or residual acrylamide monomer.	For use only as a retention aid and flocculant employed prior to the sheet-forming operation in the manufacture of paper and paperboard.
Acrylonitrile polymer, reaction product with ethylenediamine, sulfate having a nitrogen content of 22.5–25.0 percent (Kjeldahl dry basis) and containing no more than 0.075 percent monomer as ethylenediamine. The finished resin in a 24 percent by weight aqueous solution has a viscosity of 1,000–2,000 centipoises at 25° C as determined by LVT-series Brookfield viscometer using a No. 4 spindle at 30 r.p.m. (or by other equivalent method).	For use only as a size promoter and retention aid at a level not to exceed 0.5 percent by weight of the dry paper and paperboard.
Acrylonitrile polymer with styrene, reaction product with ethylenediamine, acetate, having a nitrogen content of 7.4–8.3 percent (Kjeldahl dry basis) and containing no more than 0.25 percent monomer as ethylenediamine.	1. For use only as a sizing material applied after the sheet-forming operation in the manufacture of paper and paperboard in such amount that the paper and paperboard will contain the additive at a level not in excess of 0.25 percent by weight of the dry paper and paperboard. 2. For use only as a sizing material applied prior to the sheet-forming operation in the manufacture of paper and paperboard in such amount that the paper and paperboard will contain the additive at a level not in excess of 1.0 percent by weight of the dry paper and paperboard.
(2-Alkenyl) succinic anhydrides mixture, in which the alkenyl groups are derived from olefins which contain not less than 95 percent of C_{16}–C_{18} groups.	For use only as a sizing agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 1 percent by weight of the finished dry paper and paperboard fibers.
tert-Alkyl(C_8–C_{18})mercaptans	For use only as polymerization-control agent.
Aluminum acetate	
Ammonium bis(*N*-ethyl-2-perfluoroalkylsulfonamido ethyl) phosphates, containing not more than 15% ammonium mono (*N*-ethyl-2-perfluoroalkylsulfonamido ethyl) phosphates, where the alkyl group is more than 95% C_8 and the salts have a fluorine content of 50.2% to 52.8% as determined on a solids basis.	For use only as an oil and water repellant at a level not to exceed 0.17 pound (0.09 pound of fluorine) per 1,000 square feet of treated paper or paperboard of a sheet basis weight of 100 pounds or less per 3,000 square feet of paper or paperboard, and at a level not to exceed 0.5 pound (0.26 pound of fluorine) per 1,000 square feet of treated paper or paperboard having a sheet basis weight greater than 100 lb. per 3,000 square feet as determined by analysis for total fluorine in the treated paper or paperboard without correction for any fluorine that might be present in the untreated paper or paperboard, when such paper or paperboard is used as follows: 1. In contact, under conditions of use C, D, E, F, G, or H described in table 2 of paragraph (c) of this section, with nonalcoholic food. 2. In contact with bakery products of type VII, VIII, and IX described in table I of paragraph (c) of this section under good manufacturing practices of commercial and institutional baking.

List of substances	Limitations
Ammonium persulfate	
Ammonium thiosulfate	
Azo-bisisobutyronitrile	For use only as polymerization catalyst.
Benzoyl peroxide	Do.
N,N-Bis(2-hydroxyethyl)alkyl (C_{18}–C_{18})amide	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet forming operation.
Bis(methoxymethyl)tetrakis[(octadecyloxy)-methyl] melamine resins having a 5.8–6.5 percent nitrogen content.	For use only under the following conditions: 1. As a water repellant employed prior to the sheet-forming operation in the manufacture of paper and paperboard in such amount that the finished paper and paperboard will contain the additive at a level not in excess of 1.6 percent by weight of the finished dry paper and paperboard fibers. 2. The finished paper and paperboard will be used in contact with nonalcoholic foods only.
tert-Butyl hydroperoxide	For use only as polymerization catalyst.
tert-Butyl peroxide	Do.
Calcium isostearate	For use only with *n*-decyl alcohol as a stabilizing material for aqueous calcium stearate dispersions intended for use as components of coatings for paper and paperboard.
Carrageenan and salts of carrageenan as described in §§ 172.620 and 172.626 of this chapter.	
Castor oil, hydrogenated	
Castor oil, sulfated, ammonium, potassium, or sodium salt.	
Cellulose, regenerated	
Chloracetamide	For use only as polymerization-control agent.
Cobaltous acetate	For use only as polymerization catalyst.
Cumene hydroperoxide	Do.
Cyanoguanidine	For use only: 1. As a modifier for amino resins. 2. As a fluidizing agent in starch and protein coatings for paper and paperboard.
n-Decyl alcohol	For use only with calcium isostearate as a stabilizing material for aqueous calcium stearate dispersions intended for use as components of coatings for paper and paperboard.
Dialdehyde guar gum	For use only as a wet-strength agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not to exceed 1% by weight of the finished dry paper and paperboard fibers.
Dialdehyde locust bean gum	Do.
Diallyldiethylammonium chloride polymer with acrylamide and diallyldimethylammonium chloride, produced by copolymerizing acrylamide, diallyldiethylammonium chloride and diallyldimethylammonium chloride in a weight ratio of 50–2.5–47.5, respectively, so that the finished resin in a 1 percent by weight aqueous solution has a minimum viscosity of 22 centipoises at 22° C, as determined by LVF-series Brookfield viscometer using a No. 1 spindle at 60 r.p.m. (or by other equivalent method).	For use only as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.05 percent by weight of the finished paper and paperboard.
Diallyldiethylammonium chloride polymer with acrylamide, potassium acrylate, and diallyldimethylammonium chloride. The polymer is produced by copolymerizing either: (1) acrylamide, diallyldiethylammonium chloride, and diallyldimethylammonium chloride in a weight ratio of 50–2.5–47.5, respectively, with 4.4 percent of the acrylamide subsequently hydrolyzed to potassium acrylate, or (2) acrylamide, potassium acrylate (as acrylic acid), diallyldiethylammonium chloride, and diallyldimethylammonium chloride in a weight ratio of 47.8–2.2–2.5–47.5, so that the finished resin in a 1 percent by weight aqueous solution has a minimum viscosity of 22 centipoises at 22° C, as determined by LVF-series Brookfield viscometer using a No. 1 spindle at 60 r.p.m. (or by other equivalent method).	For use only as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.05 percent by weight of the finished paper and paperboard.
Diallyldimethylammonium chloride polymer with acrylamide, reaction product with glyoxal, produced by copolymerizing not less than 90 weight percent of acrylamide and not more than 10 weight percent of diallyldimethylammonium chloride, which is then cross-linked with not more than 30 weight percent of glyoxal, such that a 10 percent aqueous solution has a minimum viscosity of 25 centipoises at 25° C as determined by Brookfield viscometer Model RVF, using a No. 1 spindle at 100 r.p.m.	For use only as a dry and wet strength agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard in such an amount that the finished paper and paperboard will contain the additive at a level not in excess of 2 percent by weight of the dry fibers in the finished paper and paperboard.
2,5-Di-*tert*-butyl hydroquinone	For use only as an antioxidant for fatty based coating adjuvants provided it is used at a level not to exceed 0.005% by weight of coating solids.
Diethanolamine	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet-forming operation.
Diethanolamine salts of mono- and bis (1*H*,1*H*,2*H*,2*H*-perfluoroalkyl) phosphates where the alkyl group is even-numbered in the range C_8–C_{18} and the salts have a fluorine content of 52.4% to 54.4% as determined on a solids basis.	For use only as an oil and water repellant at a level not to exceed 0.17 pound (0.09 pound of fluorine) per 1,000 square feet of treated paper or paperboard, as determined by analysis for total fluorine in the treated paper or paperboard without correction for any fluorine which might be present in the untreated paper or paperboard, when such paper or paperboard is used in contact with nonalcoholic foods under the conditions of use described in paragraph (c) of this section, table 2, conditions of use (B) through (H).
Diethylenetriamine	For use only as a modifier for amino resins.
N,N-Diisopropanolamide of tallow fatty acids	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet forming operation.
Dimethylamine-epichlorohydrin copolymer in which not more than 5 mole-percent of dimethylamine may be replaced by an equimolar amount of ethylenediamine and in which the ratio of total amine to epichlorohydrin does not exceed 1:1. The nitrogen content of the copolymer shall be 9.4 to 10.8 weight percent on a dry basis and a 10 percent by weight aqueous solution of the final product has a minimum viscosity of 5.0 centipoises at 25° C, as determined by LVT-series Brookfield viscometer using a No. 1 spindle at 60 r.p.m. (or by other equivalent method).	For use only as a retention aid employed before the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 1 percent by weight of the finished paper and paperboard.

List of substances	Limitations
N-[(Dimethylamino)methyl]-acrylamide polymer with acrylamide and styrene having a nitrogen content of not more than 18.9 percent and a residual acrylamide monomer content of not more than 0.2 percent on a dry basis.	For use only as a dry-strength agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not to exceed 1 percent by weight of finished dry paper or paperboard fibers.
N,N'-Dioleoylethylenediamine	
Diphenylamine	For use only as an antioxidant for fatty based coating adjuvants provided it is used at a level not to exceed 0.005% by weight of coating solids.
Dipropylene glycol	
N,N'-Distearoylethylenediamine	
α-Dodecylguanidine acetate	For use only as an antimicrobial agent in paper and paperboard under the following conditions: 1. For contact only with nonalcoholic food having a pH above 5 and provided it is used at a level not to exceed 0.4 percent by weight of the paper and paperboard. 2. For use in the outer ply of multiwall paper bags for contact with dry food of Type VIII described in Table 1 of paragraph (c) of this section and provided it is used at a level of 0.8 percent by weight of the paper.
α-Dodecylguanidine hydrochloride	For use only as an antimicrobial agent in paper and paperboard under the following conditions: 1. For contact only with nonalcoholic food having a pH above 5 and provided it is used at a level not to exceed 0.4 percent by weight of the paper and paperboard. 2. For use in the outer ply of multiwall paper bags for contact with dry food of Type VIII described in Table I of paragraph (c) of this section and provided it is used at a level of 0.8 percent by weight of the paper.
Fatty acids derived from animal and vegetable fats and oils and salts of such acids, single or mixed, as follows: Aluminum. Ammonium. Calcium. Magnesium. Potassium. Sodium. Zinc.	
Ferric chloride	
Ferrous ammonium sulfate	
Fish oil, hydrogenated	
Fish oil, hydrogenated, potassium salt	
Furcelleran and salts of furcelleran as described in §§ 172.655 and 172.660 of this chapter.	
Glycecyl lactostearate	
Glyceryl mono-12-hydroxy-stearate	
Glyceryl monoricinoleate	
Guar gum modified by treatment with β-diethylaminoethyl chloride hydrochloride.	For use only as a retention aid and/or drainage aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard.
Guar gum modified by treatment with not more than 7.6 weight percent of 2,3-epoxypropyltrimethylammonium chloride such that the finished product has a maximum chlorine content of 4.5 percent, a maximum nitrogen content of 3.0 percent, and a minimum viscosity in 1-percent-by-weight aqueous solution of 1,000 centipoises at 77° F, as determined by RV-series Brookfield viscometer (or equivalent) using a No. 3 spindle at 20 r.p.m.	For use only as a retention aid and/or internal size employed prior to the sheet-forming operation in the manufacture of paper and paperboard, and limited to use at a level not to exceed 0.15 percent by weight of the finished dry paper and paperboard fibers.
Hexamethylenetetramine	For use only as polymerization cross-linking agent for protein, including casein.
Hydroquinone and the monomethyl or monoethyl ethers of hydroquinone.	For use only as an inhibtor for monomers.
Hydroxypropyl guar gum having a minimum viscosity of 5,000 centipoises at 25° C. as determined by RV-series Brookfield viscometer using a No. 4 spindle at 20 r.p.m. (or other suitable method) and using a test sample prepared by dissolving 5 grams of moisture-free hydroxypropyl guar gum in 495 milliliters of a 70 percent by weight aqueous propylene glycol solution.	For use only as a dry strength and formation aid agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not to exceed 1.5 percent by weight of finished dry paper or paperboard fibers.
Isopropyl m- and p-cresols (thymol derived)	For use only as an antoxidant for fatty based coating adjuvants provided it is used as a level not to exceed 0.005% by weight of coating solids.
Isopropyl peroxydicarbonate	For use only as polymerization catalyst.
Japan wax	
Lanolin	
Lauryl peroxide	For use only as polymerization catalyst.
Lauryl sulfate salts: Ammonium. Magnesium. Potassium. Sodium.	
Lecithin, hydroxylated	
Lignin sulfonate and its calcium, potassium, and sodium salts.	
Methyl naphthalene sulfonic acid-formaldehyde condensate, sodium salt.	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet-forming operation.
Mineral oil, white	
Monoglyceride citrate	
Mustardseed oil, sulfated, ammonium, potassium, or sodium salt.	
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt.	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet-forming operation.
Nitrocellulose, 10.9–12.2% nitrogen	
Oleic acid, sulfated, ammonium, potassium, or sodium salt.	
N-Oleoyl-N'-stearoylethylenediamine	
Oxystearin	
Paraformaldehyde	For use only as setting agent for protein.
Petrolatum	Complying with § 178.3700 of this chapter.

List of substances	*Limitations*
Petroleum asphalt, steam and vacuum refined to meet the following specifications: Softening point 190° F—200° F, as determined by ASTM Method D-36; penetration at 77° F not to exceed 0.3 mm., as determined by ASTM Method D-5; and maximum weight loss not to exceed 3% when distilled to 700° F, nor to exceed an additional 1.1% when further distilled between 700° F and thermal decomposition.	For use only as a component of internal sizing of paper and paperboard intended for use in contact only with raw fruits, raw vegetables, and dry food of the type identified under type VIII of table 1 in paragraph (c) of this section, and provided that the asphalt is used at a level not to exceed 5% by weight of the finished dry paper and paperboard fibers.
Petroleum wax, synthetic	Complying with § 178.3720 of this chapter.
Phenothiazine	For use only as antioxidant in dry rosin size.
Phenyl acid phosphate	For use only as polymerization catalyst in melamine-formaldehyde modified alkyd coatings and limited to use at a level not to exceed 2% by weight of the coating solids.
Phenyl-β-naphthylamine	For use only as antioxidant in dry rosin size and limited to use at a level not to exceed 0.4% by weight of the dry rosin size.
Phosphoric acid esters and polyesters (and their sodium salts) of triethanolamine formed by the reaction of triethanolamine with polyphosphoric acid to produce a mixture of esters having an average nitrogen content of 1.5 percent and an average phosphorus content of 32 percent (as PO_4).	For use as an adjuvant prior to the sheet forming operation to control pitch and scale formation in the manufacture of paper and paperboard intended for use in contact with food only of the types identified in paragraph (c) of this section, table 1, under type I, IV, V, VII, VIII, and IX, and used at a level not to exceed 0.075 percent by weight of dry paper or paperboard fibers.
Poly[acrylamide-acrylic acid-*N*-(dimethyl-aminomethyl) acrylamide], produced by reacting 2.40 to 3.12 parts by weight of polyacrylamide with 1.55 parts dimethylamine and 1 part formaldehyde, and containing no more than 0.2 percent monomer as acrylamide.	For use only as a drainage aid and retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard for use in contact with fatty foods under conditions of use described in paragraph (c) of this section, table 2, conditions of use, E, F, and G.
Poly(2-aminoethyl acrylate nitrate-co-2-hydroxypropyl acrylate) produced when one mole of hydroxypropyl acrylate and three moles of acrylic acid are reacted with three moles of ethylenimine and three moles of nitric acid, such that a 35 percent by weight aqueous solution has a minimum viscosity of 150 centipoises at 72° F. as determined by RVF-series Brookfield viscometer (or equivalent) using a No. 2 spindle at 20 r.p.m.	For use only as a retention and drainage aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard at a level not to exceed 0.2 percent by weight of dry paper or paperboard fiber.
Polyacrolein (1 part) -sodium bisulfite (0.7 part) adduct, containing excess bisulfite (ratio of excess bisulfite to adduct not to exceed 1.5 to 1).	For use only as an agent in modifying starches and starch gums used in the production of paper and paperboard and limited to use at a level not to exceed 0.09 mg/in² of the finished paper and paperboard.
Polyamide-epichlorohydrin modified resin produced by reacting adipic acid with diethylene triamine to produce a basic polyamide which is modified by reaction with formic acid and formaldehyde and further reacted with epichlorohydrin in the presence of ammonium hydroxide to form a water-soluble cationic resin having a nitrogen content of 13–16 percent (Kjeldahl, dry basis) such that a 35 percent by weight aqueous solution has a minimum viscosity of 75 centipoises at 25° C, as determined by Brookfield viscosimeter using a No. 1 spindle at 12 r.p.m.	For use only as a retention aid and flocculant employed prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not to exceed 0.2 percent dry resin by weight offinished dry paper or paperboard fibers.
Polyamide-epichlorohydrin water-soluble thermosetting resins prepared by reacting adipic acid, isophthalic acid, itaconic acid or dimethyl glutarate with diethylenetriamine to form a basic polyamide and further reacting the polyamide with one of the following: Epichlorohydrin. Epichlorohydrin and ammonia mixture. Epichlorohydrin and sodium hydrosulfite mixture.	For use only in the manufacture of paper and paperboard under conditions such that the resins do not exceed 1.5 percent by weight of the paper or paperboard.
Polyamide-epichlorohydrin water-soluble thermosetting resins prepared by reacting adipic acid with diethylenetriamine to form a basic polyamide and further reacting the polyamide with an epichlorohydrin and dimethylamine mixture such that the finished resins have a nitrogen content of 17.0–18.0 percent on a dry basis, and a viscosity in 30 percent-by-weight aqueous solution of 350–800 centipoises at 20° C, as determined by a Brookfield viscometer using a No. 3 spindle at 30 r.p.m. (or equivalent method).	For use only under the following conditions: 1. As a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.12 percent by weight of the dry paper or paperboard. 2. The finished paper or paperboard will be used in contact with food only of the types identified in paragraph (c) of this section, Table 1, under types I and IVB and under conditions of use described in paragraph (c) of this section, Table 2, conditions of use (F) and (G).
Polyamine-epichlorohydrin resin produced by the reaction of bis(hexamethylene) triamine and higher homologues with epichlorohydrin such that the finished resin has a nitrogen content of 7.4–8.9 percent and chlorine content of 18–21 percent on a dry basis, and a minimum viscosity in 20 percent by weight aqueous solution of 30 centipoises at 25° C, as determined by Brookfield HAT model viscometer using a No. 1H spindle at 50 r.p.m. (or equivalent method).	For use only as a wet-strength agent and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 1 percent by weight of dry paper and paperboard fibers.
Polyamine-epichlorohydrin resin produced by the reaction of *N,N*-dimethyl-1,3-propanediamine with epichlorohydrin and further reacted with sulfuric acid, Chemical Abstracts Service Registry Number [27029-41-0], such that the finished resin has a maximum nitrogen content of 14.4 percent (dry basis) and a minimum viscosity in 30 percent by weight aqueous solution (PH 4–6) of 50 centipoises at 25° C, as determined by Brookfield LVT model viscometer, using a No. 1 spindle at 12 r.p.m. (or equivalent method).	For use only as a clarifier in the treatment of influent water to be used in the manufacture of paper and paperboard, and used at a level not to exceed 20 parts per million of the influent water.
Polyamine-epichlorohydrin water soluble thermosetting resin prepared by reacting hexamethylenediamine with 1,2-dichloroethane to form a prepolymer and further reacting this prepolymer with epichlorohydrin such that that finished resin has a nitrogen content of 5.2–5.5 percent and a chlorine content of 32.7–34.4 percent, on a dry basis, and a minimum viscosity, in 25 percent by weight aqueous solution, of 50 centipoises at 25° C, as determined on a Brookfield HAT model viscometer using a No. 1H spindle at 50 r.p.m. (or equivalent method).	For use only as a wet-strength agent and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 1 percent by weight of dry paper and paperboard fibers.

List of substances	Limitations
Polyamine-epichlorohydrin water soluble thermosetting resin prepared by reacting hexamethylenediamine with 1,2-dichloroethane to form a prepolymer and further reacting this prepolymer with epichlorohydrin. This resin is then reacted with nitrilotris (methylenephosphonic acid), pentasodium salt, such that the finished resin has a nitrogen content of 5.0–5.3 percent; a chlorine content of 29.7–31.3 percent; and a phosphorus content of 2.0–2.2 percent, on a dry basis, and a minimum viscosity, in 25 percent by weight aqueous solution, of 50 centipoises at 25°C., as determined on a Brookfield HAT model viscometer using a No. 1H spindle at 50 r.p.m. (or equivalent method).	For use only as a wet-strength agent and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 1 percent by weight of dry paper and paperboard fibers.
Polyamine resin produced by the reaction of 1,2-dichloroethane with bis(hexamethylene)triamine and higher homologues such that the finished resin has a nitrogen content of 12.0–15.0 percent on a dry basis, and a minimum viscosity in 25-percent-by-weight aqueous solution of 75 centipoises at 25° C., as determined by Brookfield HAT model viscometer using a No. 1 spindle at 50 r.p.m. (or equivalent method).	For use only as a retention aid and/or flocculent employed prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not to exceed 0.1 percent by weight of dry paper or paperboard fibers.
Polyaminoamide-epichlorohydrin modified resin produced by reacting adipic acid with diethylenetriamine to produce a polyamide which is modified by reaction with diethylaminopropylamine and further reacted with dichloroethyl ether to form a polyamide intermediate. This polyamide intermediate is then reacted with epichlorohydrin such that the finished resins have a nitrogen content of 10.9–12.4 percent (Kjeldahl, dry basis) and a minimum viscosity in 40 percent-by-weight aqueous solution of 250 centipoises at 22° C, as determined by a Brookfield Model LVT viscometer using a No. 2 spindle at 30 r.p.m. (or equivalent method).	For use only as a wet-strength agent and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 0.5 percent by weight of the finished dry paper and paperboard.
Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b) of this chapter.	For use only as provided in §§ 175.300, 178.3740 and 178.3860 of this chapter.
Poly(1,2-dimethyl-5-vinylpyridinium methyl sulfate) having a nitrogen content of 5.7 to 7.3 percent and a sulfur content of 11.7 to 13.3 percent by weight on a dry basis and having a minimum viscosity in 30-percent-by-weight aqueous solution of 2,000 centipoises at 25° C, as determined by LV-series Brookfield viscometer (or equivalent) using a No. 4 spindle at 60 r.p.m.	For use only as an adjuvant employed in the manufacture of paper and paperboard prior to the sheet-forming operation.
Polyethylene, oxidized; complying with the identity prescribed in § 177.1620(a) of this chapter.	For use only as component of coatings that contact food only of the type identified under type VII–B of table 1 in paragraph (c) of this section, and limited to use at a level not to exceed 50 percent by weight of the coating solids.
Polyethyleneamine mixture produced when 1 mole of ethylene dichloride, 1.05 moles of ammonia, and 2 moles of sodium hydroxide are made to react so that a 10 percent aqueous solution has a minimum viscosity of 40 centipoises at 77° F, as determined by Brookfield viscosimeter using a No. 1 spindle at 60 r.p.m.	For use only as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard.
Polyethylene glycol (200) dilaurate	For use only as an adjuvant employed in the manufacture of paper and paperboard prior to the sheet-forming operation.
Polyethylene glycol (400) dioleate	
Polyethylene glycol (400) esters of coconut oil fatty acids	
Polyethylene glycol (600) esters of tall oil fatty acids	
Polyethylene glycol (400) monolaurate	
Polyethylene glycol (600) monolaurate	
Polyethylene glycol (400) monooleate	
Polyethylene glycol (600) monooleate	
Polyethylene glycol (400) monostearate	
Polyethylene glycol (600) monostearate	
Polyethylene glycol (3,000) monostearate	
Polyethylenimine, produced by the polymerisation of ethylenimine.	For use only as an adjuvant employed prior to sheet formation in paper-making systems operated at a pH of 4.5 or higher, and limited to use at a level not to exceed 5% by weight of finished dry paper or paperboard fibers.
Polymethacrylic acid, sodium salt, having a viscosity in 30-percent-by-weight aqueous solution of 125–325 centipoises at 25° C as determined by LV-series Brookfield viscometer (or equivalent) using a No. 2 spindle at 60 r.p.m.	For use only as a coating adjuvant for controlling viscosity when used at a level not to exceed 0.3% by weight of coating solids.
Polymethacrylic acid, sodium salt, having a viscosity in 40-percent-by-weight aqueous solution of 400–700 centipoises at 25° C, as determined by LV-series Brookfield viscometer (or equivalent) using a No. 2 spindle at 30 r.p.m.	For use only as a coating adjuvant for controlling viscosity when used at a level not to exceed 0.1% by weight of coating solids.
Poly[(methylimino) (2-hydroxytrimethylene) hydrochloride] produced by reaction of 1:1 molar ratio of methylamine and epichlorohydrin so that a 31 percent aqueous solution at 25° C has a Stokes viscosity range of 2.5–4.0 as determined by ASTM Method D 1545–63.	For use only as a retention aid employed prior to the sheet-forming operation in such an amount that finished paper and paperboard will contain the additive at a level not in excess of 1 percent by weight of the dry paper and paperboard.
Poly [oxyethylene (dimethyliminio) ethylene (dimethyliminio) ethylene dichloride] produced by reacting equimolar quantities of *N,N,N',N'*-tetramethylethylenediamine and dichloroethyl ether to yield a solution of the solid ploymer in distilled water at 25° C with a reduced viscosity of not less than 0.15 deciliter per gram as determined by ASTM Method D 1243–66. The following formula is used for determining reduced viscosity. Reduced viscosity in terms of deciliters per gram $= \frac{t-t_0}{t_0 \times C}$, where: t = Solution efflux time. t_0 = Water efflux time. C = Concentration of solution in terms of grams per deciliter.	For use only to improve dry-strength of paper and paperboard and as a retention and drainage aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.1 percent by weight of the finished dry paper and paperboard fibers.
Polypropylene glycol (minimum molecular weight 1,000)	
Potassium persulfate	
Propylene glycol alginate	

List of substances	Limitations
Protein hydrolysate from animal hides or soybean protein condensed with oleic and/or stearic acid.	
Rapeseed oil, sulfated ammonium, potassium, or sodium salt.	
Ricebran oil, sulfated ammonium, potassium, or sodium salt.	
Rosin and rosin derivatives	As provided in § 178.3870 of this chapter.
Sodium carboxymethyl guar gum having a viscosity of 2,700–3,300 centipoises at 25° C after 24 hours as determined by RV-series Brookfield viscometer (or equivalent) using a No. 4 spindle at 20 r.p.m. and using a test sample prepared by dissolving 8 grams of sodium carboxymethyl guar gum in 392 milliliters of 0.2 percent by weight aqueous sodium o-phenylphenate solution.	For use only as a dry-strength and formation-aid agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not to exceed 1% by weight of finished dry paper or paperboard fibers.
Sodium dioctyl sulfosuccinate	
Sodium formaldehyde sulfoxylate	For use only as polymerization catalyst.
Sodium hypochlorite	
Sodium *N*-methyl-*N*-oleyltaurate	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet-forming operation.
Sodium nitrite	For use only: 1. At levels not to exceed 0.2% by weight of lubricants or release agents applied at levels not to exceed 1 lb. per ton of finished paper or paperboard. 2. As an anticorrosion agent at levels not to exceed 0.2% by weight of wax emulsions used as internal sizing in the manufacture of paper and paperboard prior to the sheet-forming operation.
Sodium persulfate	
Sodium polyacrylate	For use only: 1. As a thickening agent for natural rubber latex coatings, provided it is used at a level not to exceed 2 percent by weight of coating solids. 2. As a pigment dispersant in coatings at a level not to exceed 0.25 percent by weight of pigment.
Sperm oil, sulfated, ammonium, potassium, or sodium salt	
Stannous oleate	
Stearyl-2-lactylic acid and its calcium salt	
Styrene-maleic anhydride copolymer, sodium salt (minimum molecular weight 30,000).	For use only: 1. As a coating thickening agent at a level not to exceed 1% by weight of coating solids. 2. As surface size at a level not to exceed 1% by weight of paper or paperboard substrate.
Styrene-methacrylic acid copolymer, potassium salt (minimum molecular weight 30,000).	For use only as a coating thickening agent at a level not to exceed 1% by weight of coating solids.
Tallow	
Tallow alcohol	
Tallow alcohol, hydrogenated	
Tallow fatty acid, hydrogenated	
Tallow hydrogenated	
Tallow sulfated, ammonium, potassium, or sodium salt	
Tetraethylenepentamine	For use only as a modifier for amino resins.
N,N,N',N'-Tetramethylethylenediamine polymer with bis-(2-chloroethyl) ether, first reacted with not more than 5 percent by weight 1-chloro-2,3-epoxypropane and the reacted with not more than 5 percent by weight poly (acrylic acid) such that a 50 percent by weight aqueous solution of the product has a nitrogen content of 4.7–4.9 percent and viscosity of 350–700 centipoises at 25° C as determined by LV series Brookfield viscometer using a No. 2 spindle at 60 r.p.m. (or by other equivalent method).	For use only as a flocculent, drainage aid or retention aid employed prior to the sheet forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.2 percent by weight of the finished dry paper and paperboard fibers.
Tetrasodium *N* - (1,2 - dicarboxyethyl) - *N* - octadecylsulfosuccinamate.	For use only as an emulsifier in aqueous dispersions of rosin sizes complying with § 178.3870(a)(4) of this chapter and limited to use prior to the sheet-forming operation in the manufacture of paper and paperboard at a level not to exceed 0.02 pct by weight of finished paper and paperboard.
Triethanolamine	For use only to adjust pH during the manufacture of amino resins permitted for use as components of paper and paperboard.
Triethylene glycol adipic acid monoester produced by reacting equimolar quantities of triethylene glycol and adipic acid.	For use only as a curl-control agent at a level not to exceed 2% by weight of coated or uncoated paper and paperboard.
Triethylenetetramine	For use only as a modifier for amino resins.
Undecafluorocyclohexanemethanol ester mixture of dihydrogen phosphate, compound with 2,2'-iminodiethanol (1:1); hydrogen phosphate, compound with 2,2'-iminodiethanol (1:1); and P,P'-dihydrogen pyrophosphate, compound with 2,2'-iminodiethanol (1:2); where the ester mixture has a fluorine content of 48.3 pct to 53.1 pct as determined on a solids basis.	For use only as an oil repellent at a level not to exceed 0.087 lb (0.046 lb of fluorine) per 1,000 ft^2 of treated paper or paperboard, as determined by analysis for total fluorine in the treated paper or paperboard without correction for any fluorine which might be present in the untreated paper or paperboard, when such paper or paperboard is used in contact with food only of the types identified in paragraph (c) of this section, table 1, under types IVA, V, VIIA, VIII, and IX, and under the conditions of use B through G described in table 2 of paragraph (c) of this section.
Viscose rayon fibers	
Wax, petroleum	Complying with § 178.3710 of this chapter.
Xanthan gum, conforming to the identity and specifications prescribed in § 172.695 of this chapter, except that the residual isopropyl alcohol shall not exceed 6,000 parts per million.	For use only at a maximum level of 0.125 percent by weight of finished paper as a suspension aid or stabilizer for aqueous pigment slurries employed in the manufacture of paper and paperboard.
Xylene sulfonic acid-formaldehyde condensate, sodium salt.	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet-forming operation.
Zinc formaldehyde sulfoxylate	For use only as polymerization catalyst.
Zinc octoate	
Zirconium oxide	For use only as a component of waterproof coatings where the zirconium oxide is present at a level not to exceed 1 percent by weight of the dry paper or paperboard fiber and where the zirconium oxide is produced by hydrolysis of zirconium acetate.

(b) Substances identified in paragraph (b) (1) and (2) of this section may be used as components of the food-contact surface of paper and paperboard, provided that the food-contact surface of the paper or paperboard complies with the extractives limitations prescribed in paragraph (c) of this section.

(1) Substances identified in § 175.300 (b) (3) of this chapter with the exception of those identified in paragraph (b) (3) (v), (xv), (xx), (xxxi), and (xxxii) of that section and paragraph (a) of this section.

(2) Substances identified in this paragraph (b) (2) follow:

List of substances	*Limitations*
Acrylamide copolymerized with ethyl acrylate and/or styrene and/or methacrylic acid, subsequently reacted with formaldehyde and butyl alcohol.	For use only as coatings or components of coatings.
Acrylamide copolymerized with ethylene and vinyl chloride in such a manner that the finished copolymers have a minimum weight average molecular weight of 30,000 and contain not more than 3.5 weight percent of total polymer units derived from acrylamide, and in such a manner that the acrylamide portion may or may not be subsequently partially hydrolyzed.	
Acrylic copolymers produced by copolymerizing 2 or more of the acrylate monomers butyl acrylate, ethyl acrylate, ethyl methacrylate, methyl acrylate, methyl methacrylate, and n-propyl methacrylate, or produced by copolymerizing one or more of such acrylate monomers together with one or more of the monomers acrylic acid, acrylonitrile, butadiene, 2-ethyl-hexyl acrylate, fumaric acid, glycidyl methacrylate, n-hexyl-methacrylate, itaconic acid, methacrylic acid, styrene, vinyl acetate, vinyl chloride, and vinylidene chloride. The finished copolymers shall contain at least 50 weight percent of polymer units derived from one or more of the monomers butyl acrylate, ethyl acrylate, ethyl methacrylate, methyl acrylate, methyl methacrylate, and n-propyl methacrylate; and shall contain not more than 5 weight percent of total polymer units derived from acrylic acid, fumaric acid, glycidyl methacrylate, n-hexyl methacrylate, itaconic acid, and methacrylic acid. The provision limiting the finished acrylic copolymers to not more than 5 units derived from acrylic acid, fumaric acid, glycidyl methacrylate, n-hexyl methacrylate, itaconic acid, and methacrylic acid is not applicable to finished acrylic copolymers used as coating adjuvants at a level not exceeding 2 weight percent of total coating solids.	
n-Alkylsulfonate (alkyl group is in the range C_{10}–C_{18} with not less than 50 percent C_{16}–C_{18}).	For use only as an emulsifier for vinylidene chloride copolymer coatings and limited to use at a level not to exceed 2 percent by weight of the coating solids.
2-Bromo-4'-hydroxyacetophenone	For use only as a preservative for coating formulations, binders, pigment slurries, and sizing solutions at a level not to exceed 0.006 percent by weight of the coating, solution, slurry or emulsion.
Butylbenzyl phthalate	Complying with §178.3740 of this chapter.
Butyl oleate, sulfated, ammonium, postassium, or sodium salt.	
Butyraldehyde	
Captan (*N*-trichloromethylmercapto-4-cyclohexene-1, 2-dicarboximide).	For use only as a mold- and mildew-proofing agent in coatings intended for use in contact with food only of the types identified in paragraph (c) of this section, table 1, under type I, II, VI–B, and VIII.
Castor Oil, polyoxyethylated (42 moles ethylene oxide)	For use only as an emulsifier in nitrocellulose coatings for paper and paperboard intended for use in contact with food only of the types identified in paragraph (c) of this section, table 1, under types IV A, V, VII A, VIII, and IX; and limited to use at a level not to exceed 8 percent by weight of the coating solids.
1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	For use only as a preservative at a level of 0.3 weight percent in latexes used as pigment binders in paper and paperboard intended for use in contact with food only of the types identified in paragraph (c) of this section, table 1, under types V, VIII, and IX and under the conditions of use described in paragraph (c) of this section, table 2, conditions of use E, F, and G.
Copper 8-quinolinolate	For use only as preservative for coating formulations.
Cyclized rubber produced when natural pale crepe rubber dissolved in phenol is catalytically cyclized so that the finished cyclized rubber has a melting point of 293° F–311° F as determined by ASTM Method E–28–58T and contains no more than 4,000 p.p.m. of residual-free phenol as determined by a gas liquid chromatographic method available upon request from the Commissioner of Food and Drugs.	For use only in coatings for paper and paperboard intended for use in contact with food only of the types identified in paragraph (c) of this section, table 1, under types VIII and IX.
Dibutyl phthalate	Complying with § 178.3740 of this chapter.
Dibutyl sebacate	
Di(C_7, C_9-alkyl) adipate	
Dicyclohexyl phthalate	
Diethylene glycol ester of the adduct of terpene and maleic anhydride.	
Dihydroxy dichlorodiphenyl methane	For use only as preservative for coating formulations.
Dimethylpolysiloxane, 100 centistokes viscosity	
Dimethylpolysiloxane-beta-phenylethyl methyl polysiloxane copolymer (2:1), 200 to 400 centistokes viscosity.	
N,N' Diphenyl-*p*-phenylenediamine	For use only as polymerization inhibitor in 2-sulfoethyl methacrylate, sodium salt.
Disodium *N*-octadecylsulfosuccinamate	For use only as an emulsifier in resin latex coatings and limited to use at a level not to exceed 0.05% by weight of the coating solids.
EDTA (ethylenediaminetetraacetic acid) and its sodium and/or calcium salts.	
Ethylene-acrylic acid copolymers produced by the copolymerization of ethylene and acrylic acid and/or their partial ammonium salts. The finished copolymer shall contain no more than 25 weight-percent of polymer units derived from acrylic acid and no more than 0.35 weight percent of residual monomeric acrylic acid, and have a melt index not to exceed 350 as determined by ASTM method D 1238.	

List of substances	*Limitations*
Formaldehyde	For use only as preservative for coating formulations.
Glyoxal	For use only as an insolubilizing agent in starch- and protein-based coatings that contact nonalcoholic foods, and limited to use at a level not to exceed 6 percent by weight of the starch or protein fraction of the coating solids.
Glyceryl monobutyl ricinoleate	
Hydroxymethyl derivatives (mixture of mono and poly) of [N-(1, 1-dimethyl-3-oxobutyl) acrylamide] produced by reacting 1 mole of the [N-(1,1-dimethyl-3-oxobutyl) acrylamide] with 3 moles of formaldehyde such that the finished product has a maximum nitrogen content of 6.2 percent and a maximum hydroxyl content of 15 percent by weight on a dry basis.	For use only as a comonmoer in polyvinyl acetate latex coatings and limited to use at a level not to exceed 1 percent by weight of dry polymer solids.
Isobutyl oleate, sulfated, ammonium, potassium, or sodium salt.	
Maleic anhydride adduct of butadiene-styrene copolymer.	
α-Methylstyrene-vinyl-toluene copolymer resins (molar ratio 1 α-methylstyrene to 3 vinyltoluene).	
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt.	
Oleyl alcohol	
Oxazolidinylethylmethacrylate (CAS Registry No. 46236-15-1) copolymer with ethyl acrylate and methyl methacrylate, and containing not more than 6 percent by weight of oxazolidinylethylmethacrylate. Maximum nitrogen content shall be 0.5 percent and number average molecular weight of that portion of the copolymer soluble in tetrahydrofuran shall be not less than 50,000.	For use only as a binder for pigment coatings as a binder level not to exceed 4.0 percent by weight of dry paper or paperboard.
Pentaerythritol tetrastearate	
Petroleum alicyclic hydrocarbon resins, or the hydrogenated product thereof, meeting the following specifications: Softening point 97° C minimum, as determined by ASTM Method E 28-58T; aniline point 120° C minimum, as determined by ASTM Method D 611-64; and specific gravity 0.96-0.99 (20° C/20° C). Such petroleum hydrocarbon resins are produced by the catalytic polymerization of dienes and olefins from low-boiling distillates of cracked petroleum stocks that contain no material boiling over 200° C and that meet the ultraviolet absorbance limits prescribed in § 172.880 (b) of this chapter when subjected to the analytical procedure described in § 172.886(b) of this chapter, modified as follows: Treat the product as in the first paragraph under "Procedure" in § 172.250(b)(3) of this chapter. Then proceed with § 172.886(b) of this chapter, starting with the paragraph commencing with "Promptly complete transfer of the sample * * *".	For use only as modifiers in waxpolymer blend coatings for corrugated paperboard intended for use in bulk packaging or raw fruits, raw vegetables, iced meat iced fish, and iced poultry; and limited to use at a level not to exceed 30 weight-percent of the coating solids.
Polyester resin formed by the reaction of the methyl ester of rosin, phthalic anhydride, maleic anhydride and ethylene glycol, such that the polyester resin has an acid number of 4 to 11, a drop-softening point of 70° C-92° C., and a color of K or paler.	
Polyester resin produced by reacting the acid groups in montan wax with ethylene glycol.	
Polyethylene, oxidized	Complying with § 177.1620 of this chapter.
Polyethylene reacted with maleic anhydride such that the modified polyethylene has a saponification number not in excess of 6 after Soxhlet extraction for 24 hours with anhydrous ethyl alchol.	
Polyoxyethylated (40 moles) tallow alcohol sulfate, sodium salt.	Not to exceed 300 p.p.m. in finished coated paper or paperboard.
Polyoxypropylene-polyoxyethylene block polymers (minimum molecular weight 6,800).	
Poyvinyl acetate	
Polyvinyl alcohol (minimum viscosity of 4% aqueous solution at 20° C. of 4 centipoises).	
Polyvinyl butyral	
Polyvinyl forma	
Polyvinylidene chloride	
Polyvinyl pyrrolidone	
Polyvinyl stearate	
Propylene glycol mono- and diesters of fats and fatty acids	
Sodium decylbenzenesulfonate	
Sodium dihexyl sulfosuccinate	
Sodium *n*-dodecylpolyethoxy (50 moles) sulfate-sodium isododecylphenoxypolyethoxy (40 moles) sulfate mixtures.	For use only as an emulsifier in coatings that contact food only of the types identified in paragraph (c) of this section, table 1 ,under types IV-A, V, VII, VIII, and IX; and limited to use at levels not to exceed 0.75 percent by weight of the coating solids.
Sodium 2-ethylhexyl sulfate	
Sodium oleoyl isopropanolamide sulfosuccinate	
Sodium pentachlorophenate	For use only as preservative for coating formulations.
Sodium o-phenylphenate	Do.
Sodium vinyl sulfonate polymerized	
Styrene copolymers produced by copolymerizing styrene with maleic anhydride and its methyl and *sec*-butyl esters. Such copolymers may contain β-nitrostyrene as a polymerization chain terminator.	For use only as a coating or component of coatings and limited to use at a level not to exceed 1% by weight of paper or paperboard substrate.
Styrene-butadiene copolymers containing not more than 10 weight percent of polymer units derived by copolymerization with one or more of the following monomers: Acrylic acid. Fumaric acid. 2-Hydroxyethyl acrylate. Itaconic acid. Methacrylic acid.	
Styrene-butadiene copolymers with 2-hydroxyethyl acrylate and acrylic acid containing not more than 15 weight percent acrylic acid and no more than 20 weight percent of a combination of 2-hydroxyethyl acrylate and acrylic acid.	
Styrene-dimethylstyrene-α-methylstyrene copolymers produced by polymerizing equimolar ratios of the three comonomers such that the finished copolymers have a minimum average molecular weight of 835 as determined by ASTM Method D 2503.	For use only in coatings for paper and paperboard intended for use in contact with nonfatty food and limited to use at a level not to exceed 50% by weight of the coating solids.

List of substances	*Limitations*
Styrene-isobutylene copolymers (weight average molecular weight not less than 6,300).	For use only in coatings for paper and paperboard intended for use in contact under conditions of use D, G described in Table 2 of paragraph (c) of this section, with food of types I, II, IV–B, VI–B, VII–B, and VIII described in Table 1 of paragraph (c) of this section; and limited to use at a level not to exceed 40 percent by weight of the coating solids.
Styrene-maleic anhydride copolymers	For use only as a coating or component of coatings and limited for use at a level not to exceed 2 percent by weight of paper or paperboard substrate.
Styrene-methacrylic acid copolymers containing no more than 5 weight percent of polymer units derived from methacrylic acid.	
α-[p-(1,1,3,3-Tetramethylbutyl) phenyl]-*omega*-hydroxypoly (oxyethylene)hydrogen sulfate, sodium salt mixture with α-[p-(1,1,3,3-tetramethylbutyl)phenyl]-*omega*-hydroxypoly(oxyethylene) with both substances having a poly(oxyethylene) content averaging 3 moles.	For use only as a surface-active agent at levels not to exceed 3 percent by weight of vinyl acetate polymer with ethylene and *N*-(hydroxymethyl) acrylamide intended for use in coatings for paper and paperboard intended for use in contact with foods: 1. Of the types identified in paragraph (c) of this section, table 1, under types I, II, III, IV, VI B, and VII, and under the conditions of use described in paragraph (c) of this section, table 2, conditions of use E, F, and G. 2. Of the types identified in paragraph (c) of this section, table 1, under types V, VIII and IX and under the conditions of use described in paragraph (c) of this section, table 2, conditions of use C, D, E, F, and G.
2-Sulfoethyl methacrylate, sodium salt [C.A. Registry No. 10595–80–9].	For use only in copolymer coatings under conditions of use E, F, and G described in paragraph (c) of this section, table 2, and limited to use at a level not to exceed 1.0 percent by weight of the dry copolymer coating.
Tetrasodium *N*-(1,2-dicarboxyethyl)-*N*-octadecylsulfosuccinamate.	For use only as an emulsifier in resin latex coatings, and limited to use at a level not to exceed 0.05% by weight of the coating solids.
Toluenesulfonamide-formaldehyde resins.	
Vinyl acetate copolymers produced by copolymerizing vinyl acetate with one or more of the monomers acrylamide, acrylic acid, acrylonitrile, bicyclo-[2.2.1]*hept*-2-ene-6-methylacrylate, butyl acrylate, crotonic acid, decyl acrylate, diallyl fumarate, diallyl maleate, diallyl phthalate, dibutyl fumarate dibutyl itaconate, dibutylmaleate, di(2-ethylhexyl) maleate, divinyl benzene, ethyl acrylate, 2-ethyl-hexyl acrylate, fumaric acid, itaconic acid, maleic acid, methacrylic acid, methyl acrylate, methyl methacrylate, mono(2-ethylhexyl) maleate, monoethyl maleate, styrene, vinyl butyrate, vinyl crotonate, vinyl hexoate, vinylidene chloride, vinyl pelargonate, vinyl propionate, vinyl pyrrolidone, vinyl stearate, and vinyl sulfonic acid. The finished copolymers shall contain at least 50 weight percent of polymer units derived from vinyl acetate and shall contain no more than 5 weight percent of total polymer units derived from acrylamide, acrylic acid, crotonic acid, decyl acrylate, dibutyl itaconate, di(2-ethylhexyl) maleate, fumaric acid, itaconic acid, maleic acid, methacrylic acid, mono(2-ethylhexyl) maleate, monoethyl maleate, vinyl butyrate, vinyl hexoate, vinyl pelargonate, vinyl propionate, vinyl stearate, and vinyl sulfonic acid.	
Vinyl acetate polymer with ethylene and *N*-(hydroxymethyl) acrylamide containing not more than 6 weight percent of total polymer units derived from *N*-(hydroxymethyl) acrylamide.	For use only in coatings for paper and paperboard intended for use in contact with foods: 1. Of the types identified in paragraph (c) of this section, table 1, under types I, II, III, IV, VI B, and VII and under the conditions of use described in paragraph (c) of this section, table 2, conditions of use E, F, and G. 2. Of the types identified in paragraph (c) of this section, table 1, under types V, VIII, and IX and under the conditions of use described in paragraph (c) of this section, table 2, conditions of use C, D, E, F, and G.
Vinyl chloride copolymers produced by copolymerizing vinyl chloride with one or more of the monomers acrylonitrile; fumaric acid and its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters; maleic acid and its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters; maleic anhydride; 5-norbornene-2, 3-dicarboxylic acid; mono-*n*-butyl ester; vinyl acetate; and vinylidene chloride. The finished copolymers shall contain at least 50 weight percent of polymer units derived from vinyl chloride; shall contain no more than 5 weight percent of total polymer units derived from fumaric and/or maleic acid and/or their methyl, ethyl, propyl, butyl, amyl, heptyl, or octyl monoesters or from maleic anhydride or from mono-*n*-butyl ester of 5-norbornene-2, 3-dicarboxylic acid (however, in any case the finished copolymers shall contain no more than 4 weight percent of total polymer units derived from mono-*n*-butyl ester of 5-norbornene-2,3-dicarboxylic acid).	
Vinyl chloride-vinyl acetate hydroxyl-modified copolymers.	
Vinyl chloride-vinyl acetate hydroxyl-modified copolymers reacted with trimellitic anhydride.	
Vinylidene chloride copolymers produced by copolymerizing vinylidene chloride with one or more of the monomers acrylamide, acrylic acid, acrylonitrile, butyl acrylate, butyl methacrylate, ethyl acrylate, ethyl methacrylate, fumaric acid, itaconic acid, methacrylic acid, methyl acrylate, methyl methacrylate, octadecyl methacrylate, propyl acrylate, propyl methacrylate, vinyl chloride, and vinyl sulfonic acid. The finished copolymers shall contain at least 50 weight percent of polymer units derived from vinylidene chloride; and shall contain no more than 5 weight percent of total polymer units derived from acrylamide, acrylic acid, fumaric acid, itaconic acid, methacrylic acid, octadecyl methacrylate, and vinyl sulfonic acid.	

(c) The food-contact surface of the paper and paperboard in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of this paragraph, shall yield net chloroform-soluble extractives (corrected for wax, petrolatum, mineral oil and zinc extractives as zinc oleate) not to exceed 0.5 milligram per square inch of food-contact surface as determined by the methods described in paragraph (d) of this section.

TABLE 1—TYPES OF RAW AND PROCESSED FOODS

I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).

II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.

III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.

IV. Dairy products and modifications:
- A. Water-in-oil emulsions, high- or low-fat.
- B. Oil-in-water emulsions, high- or low-fat.

V. Low-moisture fats and oil.

VI. Beverages:
- A. Containing up to 8 percent of alcohol.
- B. Nonalcoholic.
- C. Containing more than 8 percent alcohol.

VII. Bakery products other than those included under types VIII or IX of this table:
- A. Moist bakery products with surface containing free fat or oil.
- B. Moist bakery products with surface containing no free fat or oil.

VIII. Dry solids with the surface containing no free fat or oil (no end test required).

IX. Dry solids with the surface containing free fat or oil.

TABLE 2.—*Test procedures with time temperature conditions for determining amount of extractives from the food-contact surface of uncoated or coated paper and paperboard, using solvents simulating types of foods and beverages*

Condition of use	Types of food (see table 1)	Food-simulating solvents			
		Water (*time and temperature*)	Heptane [1] (*time and temperature*)	8 pct alcohol (*time and temperature*)	50 pct alcohol (*time and temperature*)
A. High temperature heat-sterilized (e.g., over 212° F).	I, IV–B, VII–B	250° F, 2 hr.			
	III, IV–A, VII–A	do	150° F, 2 hr.		
B. Boiling water sterilized	II, VII–B	212° F, 30 min.			
	III, VII–A	do	120° F, 30 min.		
C. Hot filled or pasteurized above 150° F.	II, IV–B, VII–B	Fill boiling, cool to 100° F.			
	III, IV–A, VII–A	do	120° F, 15 min.		
	V, IX		do		
D. Hot filled or pasteurized below 150° F.	II, IV–B, VI–B, VII–B	150° F, 2 hr.			
	III, IV–A, VII–A	do	100° F, 30 min.		
	V, IX		do		
	VI–A		do	150° F, 2 hr.	
	VI–C				150° F, 2 hr.
E. Room temperature filled and stored (no thermal treatment in the container).	I, II, IV–B, VI–B, VII–B	120° F, 24 hr.			
	III, IV–A, VII–A	do	70° F, 30 min.		
	V, IX		do		
	VI–A			120° F, 24 hr.	
	VI–C				120° F, 24 hr.
F. Refrigerated storage (no thermal treatment in the container).	III, IV–A, VII–A	70° F, 48 hr.	70° F, 30 min.		
	I, II, IV–B, VI–B, VII–B	do			
	VI–A			70° F, 48 hr.	
	VI–C				70° F, 48 hr.
G. Frozen storage (no thermal treatment in the container).	I, II, IV–B, VII–B	70° F, 24 hr.			
	III, VII–A	do	70° F, 30 min.		
H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:					
1. Aqueous or oil-in-water emulsion of high- or low-fat.	I, II, IV–B, VII–B	212° F, 30 min.			
2. Aqueous, high- or low-free oil or fat.	III, IV–A, VII–A, IX	do	120° F, 30 min.		

[1] Heptane extractability results must be divided by a factor of five in arriving at the extractability for a food product having water-in-oil emulsion or free oil or fat. Heptane food-simulating solvent is not required in the case of wax-polymer blend coatings for corrugated paperboard containers intended for use in bulk packaging of iced meat, iced fish, and iced poultry.

(d) *Analytical methods*—(1) *Selection of extractability conditions.* First ascertain the type of food product (table 1, paragraph (c) of this section) that is being packed commercially in the paper or paperboard and the normal conditions of thermal treatment used in packaging the type of food involved. Using table 2, paragraph (c) of this section, select the food-simulating solvent or solvents and the time-temperature exaggerations of the paper or paperboard use conditions. Having selected the appropriate food-simulating solvent or solvents and the time-temperature exaggeration over normal use, follow the applicable extraction procedure.

(2) *Reagents*—(i) *Water.* All water used in extraction procedures should be freshly demineralized (deionized) distilled water.

(ii) *n-Heptane.* Reagent grade, freshly redistilled before use, using only material boiling at 208° F.

(iii) *Alcohol.* 8 or 50 percent (by volume), prepared from undenatured 95 percent ethyl alcohol diluted with demineralized (deionized) distilled water.

(iv) *Chloroform.* Reagent grade, freshly redistilled before use, or a grade having an established consistently low blank.

(3) *Selection of test method.* Paper or paperboard ready for use in packaging shall be tested by use of the extraction cell described in "Official Methods of Analysis of the Association of Official Agricultural Chemists," 10th edition, 1965, sections 7.034–7.039, under "Exposing Flexible Barrier Materials for Extraction," also described in ASTM Method F 34–63T, except that formed paper and paperboard products may be tested in the container by adapting the in-container methods described in § 175.300(e) of this chapter. Formed paper and paperboard products such as containers and lids, that cannot be tested satisfactorily by any of the above methods may be tested in specially designed extraction equipment, usually consisting of clamping devices that fit the closure or container so that the food-contact surface can be tested, or, if flat samples can be cut from the formed paper or paperboard products without destroying the integrity of the food-contact surface, they may be tested by adapting the following "sandwich" method:

(i) *Apparatus.* (*a*) Thermostated (±1.0° F) water bath, variable between 70° F and 120 F. water bath cover capable of holding at least one 800-milliliter beaker partially submersed in bath.

(*b*) Analytical balance sensitive to 0.1 milligram with an approximate capacity of 100 grams.

(*c*) Tongs.

(*d*) Hood and hot-plate facilities.

(*e*) Forced draft oven.

For each extraction, the following additional apparatus is necessary:

(*f*) One No. 2 paper clip.

(*g*) One 800-milliliter beaker with watch-glass cover.

(*h*) One 250-milliliter beaker.

(*i*) Five 2½-inch-square aluminum screens (standard aluminum window screening is acceptable).

(*j*) One wire capable of supporting sample stack.

(ii) *Procedure.* (*a*) For each extraction, accurately cut eight 2½-inch-square samples from the formed paper or paperboard product to be tested.

(*b*) Carefully stack the eight 2½-inch-square samples and the five 2½-inch-square aluminum screens in sandwich form such that the food-contact side of

each sample is always next to an aluminum screen, as follows: Screen, sample, sample, screen, sample, sample, screen, etc. Clip the sandwich together carefully with a No. 2 paper clip, leaving just enough space at the top to slip a wire through.

(c) Place an 800-milliliter beaker containing 100-milliliters of the appropriate food-simulating solvent into the constant temperature bath, cover with a watch glass and condition at the desired temperature.

(d) After conditioning, carefully lower the sample sandwich with tongs into the beaker.

(e) At the end of the extraction period, using the tongs, carefully lift out the sample sandwich and hang it over the beaker with the wire.

(f) After draining, pour the food-simulating solvent solution into a tared 250-milliliter beaker. Rinse the 800-milliliter beaker three times, using a total of not more than 50 milliliters of the required solvent.

(g) Determine total nonvolatile extractives in accordance with paragraph (d)(5) of this section.

(4) *Selection of samples.* Quadruplicate samples should be tested, using for each replicate sample the number of cups, containers, or preformed or converted products nearest to an area of 100 square inches.

(5) *Determination of amount of extractives*—(i) *Total residues.* At the end of the exposure period, remove the test container or test cell from the oven and combine the solvent for each replicate in a clean Pyrex (or equivalent) flask or beaker being sure to rinse the test container or cell with a small quantity of clean solvent. Evaporate the food-simulating solvents to about 100 milliliters in the flask or beaker, and transfer to a clean, tared evaporating dish (platinum or Pyrex), washing the flask three times with small portions of solvent used in the extraction procedure, and evaporate to a few milliliters on a nonsparking, low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at a temperature of aproximately 221° F. Cool the evaporating dish in a desiccator for 30 minutes and weigh the residue to the nearest 0.1 milligram, (e). Calculate the extractives in milligrams per square inch of the container or sheeted paper or paperboard surface.

(a) *Water and 8- and 50-percent alcohol.* Milligrams extractives per square inch $=\frac{e}{s}$

(b) *Heptane.* Milligrams extractives per square inch $=\frac{e}{(s)\ (F)}$.

Where:

e = Milligrams extractives per sample tested.

s = Surface area tested, in square inches.

F = Five, the ratio of the amount of extractives removed by heptane under exaggerated time-temperature test conditions compared to the amount extracted by a fat or oil under exaggerated conditions of thermal sterilization and use.

e' = Chloroform-soluble extractives residue.

ee' = Corrected chloroform-soluble extractives residue.

e' or ee' is substituted for e in the above equations when necessary.

If when calculated by the equations in paragraph (d)(5)(i) (*a*) and (*b*) of this section, the extractives in milligrams per square inch exceed the limitations perscribed in paragraph (c) of this section, proceed to paragraph (d)(5)(ii) of this section (method for determining the amount of chloroform-soluble extractives residues).

(ii) *Chloroform-soluble extractives residue.* Add 50 milliliters of chloroform (freshly distilled reagent grade or a grade having an established consistently low blank) to the dried and weighed residue, (e), in the evaporating dish obtained in paragraph (d)(5)(i) of this section. Warm carefully, and filter through Whatman No. 41 filter paper (or equivalent) in a Pyrex (or equivalent) funnel, collecting the filtrate in a clean, tared evaporating dish (platinum or Pyrex). Repeat the chloroform extraction, washing the filter paper with this second portion of chloroform. Add this filtrate to the original filtrate and evaporate the total down to a few milliliters on a low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at approximately 221° F. Cool the evaporating dish in a desiccator for 30 minutes and weigh to the nearest 0.1 milligram to get the chloroform-soluble extractives residue (e'). This e' is substituted for e in the equations in paragraph (d)(5)(i) (*a*) and (*b*) of this section. If the chloroform-soluble extractives in milligrams per square inch still exceeds the limitation prescribed in paragraph (c) of this section, proceed to paragraph (d)(5)(iii) of this section (method for determining corrected chloroform-soluble extractives residue).

(iii) *Corrected chloroform-soluble extractives residue*—(*a*) *Correction for zinc extractives.* Ash the residue in the evaporating dish by heating gently over a Meker-type burner to destroy organic matter and hold at red heat for about 1 minute. Cool in the air for 3 minutes, and place the evaporating dish in the desiccator for 30 minutes and weigh to the nearest 0.1 milligram. Analyze this ash for zinc by standard Association of Official Agricultural Chemists methods or equivalent. Calculate the zinc in the ash as zinc oleate, and subtract from the weight of chloroform-soluble extractives residue (e') to obtain the zinc-corrected chloroform-soluble extractives residue (ee'). This ee' is substituted for e in the equations in paragraph (d)(5)(i) (*a*) and (*b*) of this section.

(b) *Correction for wax, petrolatum, and mineral oil*—(*1*) *Apparatus.* Standard 10 millimeter inside diameter x 60 centimeter chromatographic column (or standard 50-milliliter buret with an inside diameter of 10–11 millimeters) with a stopcock of glass, perfluorocarbon resin, or equivalent material. The column (or buret) may be optionally equipped with an integral coarse, fritted glass disc and the top of the column (or buret) may be optionally fitted with a 100-millimeter solvent reservoir.

(2) *Preparation of column.* Place a snug pledget of fine glass wool in the bottom of the column (or buret) if the column (or buret) is not equipped with integral coarse, fritted glass disc. Overlay the glass wool pledget (or fritted glass disc) with a 15–20 millimeter deep layer of fine sand. Measure in a graduated cylinder 15 milliliters of chromatographic grade aluminum oxide (80–200 mesh) that has been tightly settled by tapping the cylinder. Transfer the aluminum oxide to the chromatographic tube, tapping the tube during and after the transfer so as to tightly settle the aluminum oxide. Overlay the layer of aluminum oxide with a 1.0–1.5 centimeter deep layer of anhydrous sodium sulfate and on top of this place an 8–10 millimeter thick plug of fine glass wool. Next carefully add about 25 milliliters of heptane to the column with stopcock open, and allow the heptane to pass through the column until the top level of the liquid just passes into the top glass wool plug in the column, and close stopcock.

(3) *Chromatographing of sample extract*—(i) *For chloroform residues weighing 0.5 gram or less.* To the dried and weighed chloroform-soluble extract residue in the evaporating dish, obtained in paragraph (d)(5)(ii) of this section, add 20 milliliters of heptane and stir. If necessary, heat carefully to dissolve the residue. Additional heptane not to exceed a total volume of 50 milliliters may be used if necessary to complete dissolving. Cool to room temperature. (If solution becomes cloudy, use the procedure in paragraph (d)(5)(iii) (*b*)(*3*)(*ii*) of this section to obtain and aliquot of heptane solution calcuated to contain 0.1–0.5 gram of chloroform-soluble extract residue.) Transfer the clear liquid solution to the column (or buret). Rinse the dish with 10 millimeters of additional heptane and add to column. Allow the liquid to pass through the column into a clean, tared evaporating dish(platinum or Pyrex) at a dropwise rate of about 2 milliliters per minute until the liquid surface reaches the top glass wool plug; then close the stopcock temporarily. Rinse the Pyrex flask which contained the filtrate with an additional 10–15 milliliters of heptane and add to the column. Wash (elute) the column with more heptane collecting about 100 milliliters of total eluate including that already collected in the evaporating dish. Evaporate the combined eluate in the evaporating dish to dryness on a steam bath. Dry the residue for 15 minutes in an oven maintained at a temperature of approximately 221° F. Cool the evaporating dish in a disccator for 30 minutes and weigh the residue to the nearest 0.1 milligram. Subtract the weight of the residue from the weight of chloroform-soluble extractives residue (e') to obtain the wax-, petrolatum-, and mineral oil-corrected chloroform-soluble extractives residue (ee'). This ee' is substituted for e in the equations in paragraph (d)(5)(i) (*a*) and (*b*) of this section.

(ii) *For chloroform residues weighing more than 0.5 gram.* Redissolve the

dried and weighed chloroform-soluble extract residue as described in paragraph (d)(5)(iii)(*b*)(*3*)(*i*) of this section using proportionately larger quantities of heptane. Transfer the heptane solution to an appropriate-sized volumetric flask (i.e., a 250-milliliter flask for about 2.5 grams of residue) and adjust to volume with additional heptane. Pipette out an aliquot (about 50 milliliters) calculated to contain 0.1–0.5 gram of the chloroform-soluble extract residue and analyze chromatographically as described in paragraph (d)(5)(iii)(*b*)(*3*)(*i*) of this section. In this case the weight of the dried residue from the heptane eluate must be multiplied by the dilution factor to obtain the weight of wax, petrolatum, and mineral oil residue to be subtracted from the weight of chloroform-soluble extractives residue (*e'*) to obtain the wax-, petrolatum-, and mineral oil-corrected chloroform-soluble extractives residue (*ee'*). This *ee'* is substituted for *e* in the equations in paragraph (d)(5)(i)(*a*) and (*b*) of this section. (Note: In the case of chloroform-soluble extracts which contain high melting waxes (melting point greater than 170° F), it may be necessary to dilute the heptane solution further so that a 50-milliliter aliquot will contain only 0.1–0.2 gram of the chloroform-soluble extract residue.)

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter, except where the copolymers are restricted to use in contact with food only of the type identified in paragraph (c), table 1 under category VIII.

§ 176.180 Components of paper and paperboard in contact with dry food.

The substances listed in this section may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding dry food of the type identified in § 176.170 (c), table 1, under type VIII, subject to the provisions of this section.

(a) The substances are used in amounts not to exceed that required to accomplish their intended physical or technical effect, and are so used as to accomplish no effect in food other than that ordinarily accomplished by packaging.

(b) The substances permitted to be used include the following:

(1) Substances that by § 176.170 and other applicable regulations in Parts 170 through 189 of this chapter may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard, subject to the provisions of such regulation.

(2) Substances identified in the following list:

List of substances	*Limitations*
4-[2-[2-(2-alkoxy(C_{12}–C_{15}) ethoxy) ethoxy]ethyl]disodium sulfosuccinate.	For use as a polymerization emulsifier and latex emulsion stabilizer at levels not to exceed 5 percent by weight of total emulsion solids.
Aluminum and calcium salts of FD & C dyes on a substrate of alumina.	Colorant.
Ammonium nitrate	
Amylose	
Barium metaborate	For use as preservative in coatings and sizings.
N,N'-Bis(hydroxyethyl)lauramide	
Bis(trichloromethyl) sulfone C.A. Registry No. 3064708	For use only as a preservative in coatings.
Borax	For use as preservative in coatings.
Boric acid	Do.
sec-Butyl alcohol	
Butyl benzyl phthalate	
Candelilla wax	
Carbon tetrachloride	
Castor oil, polyoxyethylated (42 moles ethylene oxide)	
Chloral hydrate	Polymerization reaction-control agent.
N-Cyclohexyl-*p*-toluene sulfonamide	
2,5-Di-*tert*-butyl hydroquinone	
Diethanolamine	
Diethylene glycol monobutyl ether	
Diethylene glycol monoethyl ether	
Diethylenetriamine	
N,N-Diisopropanolamide of tallow fatty acids	
N-[(dimethylamino)methyl]acrylamide polymer with acrylamide and styrene.	
N,N'-Dioleoylethylenediamine, *N,N'*-dilinoleoylethylenediamine, and *N*-oleoyl-*N'*-linoleoylethylenediamine mixture produced when tall oil fatty acids are made to react with ethylenediamine such that the finished mixture has a melting point of 212°–228° F, as determined by ASTM Method D 127–60, and an acid value of 10 maximum.	
Diphenylamine	
Disodium *N*-octadecylsulfosuccinamate	
tert-Dodecyl thioether of polyethylene glycol	
Erucamide (erucylamide)	
Ethylene oxide	Fumigant in sizing.
Ethylene oxide adduct of mono-(2-ethylhexyl) o-phosphate.	
Fatty acid (C_{12}–C_{18}) diethanolamide	
Fish oil fatty acids, hydrogenated, potassium salt	
Formaldehyde	
Glyceryl monocaprate	
Glyoxal	

List of substances	Limitations
Hexamethylenetetramine	Polymerization crosslinking agent for protein, including casein. As neutralizing agent with myristochromic chloride complex and stearato-chromic chloride complex.
Hexylene glycol (2-methyl-2,4-pentanediol)	
Hydroabietyl alcohol	
Isopropanolamine hydrochloride	
Isopropyl *m*- and *p*-cresol (thymol derived)	
Itaconic acid	
Maleic anhydride-diisobutylene copolymer, ammonium or sodium salt.	
Melamine-formaldehyde modified with:	Basic polymer.
Alcohols (ethyl, butyl, isobutyl, propyl, or isopropyl).	
Diethylenetriamine.	
Imino-bis-butylamine.	
Imino-bis-ethyleneimine.	
Imino-bis-propylamine.	
Polyamines made by reacting ethylenediamine or trimethylenediamine with dichloroethane or dichloropropane.	
Sulfanilic acid.	
Tetraethylenepentamine.	
Triethylenetetramine.	
Methyl alcohol	
Methyl esters of mono-, di-, and tripropylene glycol	
Methyl naphthalene sulfonic acid-formaldehyde condensate, sodium salt.	
Modified polyacrylamide resulting from an epichlorohydrin addition to a condensate of formaldehyde-dicyandiamide-diethylene triamine and which product is then reacted with polyacrylamide and urea to produce a resin having a nitrogen content of 5.6 to 6.3 percent and having a minimum viscosity in 56 percent-by-weight aqueous solution of 200 centipoises at 25° C, as determined by LVT-series Brookfield viscometer using a No. 4 spindle at 60 r.p.m. (or equivalent method).	For use only as a dry strength and pigment retention aid agent employed prior to the sheetforming operation in the manufacture of paper and paperboard and used at a level not to exceed 1 percent by weight of dry fibers.
Monoglyceride citrate	
Myristo chromic chloride complex	
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt.	
Nickel	
β-Nitrostyrene	Basic polymer.
α-*cis*-9-Octadecenyl-*omega*-hydroxypoly-(oxyethylene); the octadecenyl group is derived from oleyl alcohol and the poly(oxyethylene) content averages not less than 20 moles.	
α-(*p*-Nonylphenyl)-*omega*-hydroxypoly (oxyethylene) sulfate, ammonium salt; the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content averages 9 or 30 moles.	
Oleic acid reacted with *N*-alkyl-(C_{16}-C_{18}) trimethylenediamine.	
Petroleum alicyclic hydrocarbon resins, or the hydrogenated product thereof, complying with the identity prescribed in § 176.170(b)(2).	For use as modifiers at levels up to 30 weight-percent of the solids content of wax-polymer blend coatings.
Petroleum hydrocarbon resin (produced by the catalytic polymerization and subsequent hydrogenation of styrene, vinyltoluene, and indene types from distillates of cracked petroleum stocks).	
Petroleum hydrocarbons, light and odorless	
Petroleum sulfonates	
Pine oil	
Poly(2-aminoethyl acrylate nitrate-co-2-hydroxypropyl acrylate) complying with the identity described in § 176.170(a).	
Polyamide-epichlorohydrin modified resins resulting from the reaction of the initial caprolactam-itaconic acid product with diethylenetriamine and then condensing this prepolymer with epichlorohydrin to form a cationic resin having a nitrogen content of 11–15 percent and chlorine level of 20–23 percent on a dry basis.	
Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b) of this chapter.	
Poly [2-(diethylamino) ethyl methacrylate] phosphate	
Polyethylene glycol (200) dilaurate	
Polymers: Homopolymers and copolymers of the following monomers:	Basic polymer.
Acrylamide.	
Acrylic acid and its methyl, ethyl, butyl, propyl, or octyl esters.	
Acrylonitrile.	
Butadiene.	
Crotonic acid.	
Cyclol acrylate.	
Decyl acrylate.	
Diallyl fumarate.	
Diallyl maleate.	
Diallyl phthalate.	
Dibutyl fumarate.	
Dibutyl itaconate.	
Dibutyl maleate.	
Di(2-ethylhexyl) maleate.	
Dioctyl fumarate.	
Dioctyl maleate.	
Divinylbenzene.	
Ethylene.	
2-Ethylhexyl acrylate.	
Fumaric acid.	
Glycidyl methacrylate.	
2-Hydroxyethyl acrylate.	
Isobutyl acrylate.	
Isobutylene.	
Isoprene.	
Itaconic acid.	
Maleic anhydride and its methyl or butyl esters.	

List of substances	*Limitations*
Polymers: Homopolymers and copolymers of the following monomers—continued	
Methacrylic acid and its methyl, ethyl, butyl, or propyl esters.	
Methylstyrene.	
Mono(2-ethylhexyl) maleate.	
Monoethyl maleate.	
5-Norbornene-2,3-dicarboxylic acid, mono-*n*-butyl ester.	
Styrene.	
Vinyl acetate.	
Vinyl butyrate.	
Vinyl chloride.	
Vinyl crotonate.	
Vinyl hexoate.	
Vinylidene chloride.	
Vinyl pelargonate.	
Vinyl propionate.	
Vinyl pyrrolidone.	
Vinyl stearate.	
Vinyl sulfonic acid.	
Polyoxyethylene (minimum 12 moles) ester of tall oil (30%–40% rosin acids).	
Polyoxypropylene-polyoxyethylene glycol (minimum molecular weight 1,900).	
Polyvinyl alcohol.	
Potassium titanate fibers produced by calcining titanium dioxide, potassium chloride, and potassium carbonate, such that the finished crystalline fibers have a nominal diameter of 0.20–0.25 micron, a length-to-diameter ratio of approximately 25:1 or greater, and consist principally of $K_2Ti_4O_9$ and $K_2Ti_6O_{13}$.	
Sodium diisobutylphenoxy diethoxyethyl sulfonate.	
Sodium diisobutylphenoxy monoethoxy ethylsulfonate.	
Sodium *n*-dodecylpolyethoxy (50 moles) sulfate.	
Sodium isododecylphenoxypolyethoxy (40 moles) sulfate.	
Sodium *N*-methyl-*N*-oleyl taurate.	
Sodium methyl siliconate.	
Sodium nitrite.	
Sodium polyacrylate.	
Sodium bis-tridecylsulfosuccinate.	
Sodium xylene sulfonate.	
Sorbose.	
Stearato chromic chloride complex.	
Styrene-allyl alcohol copolymers.	
Styrene-methacrylic acid copolymer, potassium salt.	
Tetraethylenepentamine.	Polymerization cross-linking agent.
α-[*p*-(1,1,3,3-Tetramethylbutyl)phenyl]-*omega*-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and their sodium, potassium, and ammonium salts having a poly(oxyethylene) content averaging 6–9 or 40 moles.	
α-[*p*-(1,1,3,3-Tetramethylbutyl)phenyl or *p*-nonylphenyl]-*omega*-hydroxypoly(oxyethylene) where nonyl group is a propylene trimer isomer.	
Tetrasodium *N*-(1,2-dicarboxyethyl)-*N*-octadecyl sulfosuccinamate.	
Toluene.	
Triethanolamine.	
Triethylenetetramine.	Polymerization cross-linking agent.
Triethylenetetramine monoacetate, partially stearoylated.	
Urea-formaldehyde chemically modified with:	
Alcohol (methyl, ethyl, butyl, isobutyl, propyl, or isopropyl).	
Aminomethylsulfonic acid.	
Diaminobutane.	
Diaminopropane.	
Diethylenetriamine.	
N,N'-Dioleoylethylenediamine.	
Diphenylamine.	
N,N'-Distearoylethylenediamine.	
Ethylenediamine.	
Guanidine.	
Imino-bis-butylamine.	
Imino-bis-ethylamine.	
Imino-bis-propylamine.	
N-Oleoyl-*N'*-stearoylethylenediamine.	
Polyamines made by reacting ethylenediamine or triethylenediamine with dichloroethane or dichloropropane.	
Tetraethylenepentamine.	
Triethylenetetramine.	
Xylene.	
Xylene sulfonic acid-formaldehyde condensate, sodium salt.	
Zinc stearate.	

§ 176.200 Defoaming agents used in coatings.

The defoaming agents described in this section may be safely used as components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The defoaming agents are prepared as mixtures of substances described in paragraph (d) of this section.

(b) The quantity of any substance employed in the formulation of defoaming agents does not exceed the amount reasonably required to accomplish the intended physical or technical effect in the defoaming agents or any limitation further provided.

(c) Any substance employed in the production of defoaming agents and which is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

(d) Substances employed in the formulation of defoaming agents include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in defoaming agents and used in accordance with such sanction or approval.

(3) Substances identified in this paragraph (d)(3) and subject to such limitations as are provided:

List of substances	*Limitations*
n-Butyl alcohol	
tert-Butyl alcohol	
Butyl stearate	
Castor oil, sulfated, ammonium, potassium, or sodium salt.	
Cetyl alcohol	
Cyclohexane	
Cyclohexanol	
Diethylene glycol monolaurate	
Diethylene glycol monostearate	
Dimers and trimers of unsaturated C_{18} fatty acids derived from: Animal and vegetable fats and oils. Tall oil.	For use only at levels not to exceed 0.1% by weight of total coating solids.
Dimethylpolysiloxane	
Dipropylene glycol	
Ethyl alcohol	
Fats and oils derived from animal, marine, or vegetable sources:	
Fatty acids derived from animal, marine, or vegetable fats and oils, and salts of such acids, single or mixed, as follows: Aluminum. Ammonium. Calcium. Magnesium. Potassium. Sodium. Zinc.	
Formaldehyde	For use as preservative of defoamer only.
Glyceryl mono-12-hydroxystearate	
Glyceryl monostearate	
Hexane	
Hexylene glycol (2-methyl-2,4-pentanediol)	
Isobutyl alcohol	
Isopropyl alcohol	
Kerosene	
Lecithin hydroxylated	
Methyl alcohol	
Methylcellulose	
Methyl esters of fatty acids derived from animal, marine, or vegetagle fats and oils.	
Methyl oleate	
Methyl palmitate	
Mineral oil	
Mustardseed oil, sulfated, ammonium, potassium, or sodium salt.	
Myristyl alcohol	
Naphtha	
β-Naphthol	For use as preservative of defoamer only.
Nonylphenol	
Odorless light petroleum hydrocarbons	As defined in § 178.3650 of this chapter.
Oleic acid, sulfated, ammonium, potassium, or sodium salt.	
Parachlorometacresol	For use as preservative of defoamer only.
Peanut oil, sulfated, ammonium, potassium, or sodium salt.	
Petrolatum	
Pine oil	
Polyacrylic acid, sodium salt	As a stabilizer and thickener in defoaming agents containing dimethylpolysiloxane.
Polyethylene	
Polyethylene, oxidized	
Polyethylene glycol (200) dilaurate	
Polyethylene glycol (400) dioleate	
Polyethylene glycol (600) dioleate	
Polyehtylene glycol (400) esters of coconut oil fatty acids	
Polyethylene glycol (400) monooleate	
Polyethylene glycol (600) monooleate	
Polyethylene glycol (600) monoricinoleate	
Polyethylene glycol (400) monostearate	
Polyoxybutylene-polyoxypropylene-polyoxyethylene glycol (min. mol. wt. 3,700).	
Polyoxyethylated (min. 3 mols) cetyl alcohol	
Polyoxyethylated (min. 5 mols) oleyl alcohol	
Polyoxyethylated (min. 1.5 mols) tridecyl alcohol	
Polyoxyethylene (min. 15 mols) ester of rosin	
Polyoxyethylene (min. 8 mols) monooleate	
Polyoxyethylene (40) stearate	
Polyoxypropylated (min. 20 mols) butyl alcohol	
Polyoxypropylene glycol (min. mol. wt. 200)	
Polyoxypropylene (min. 20 mols) oleate butyl ether	
Polyoxypropylene-polyoxyethylene glycol (min. mol. wt. 1,900).	
Polyoxypropylene (min. 40 mols) stearate butyl ether	
Potassium pentachlorophenate	For use as preservative of defoamer only.
Potassium trichlorophenate	For use as preservative of defoamer only.
Propylene glycol monoester of soybean oil fatty acids	
Propylene glycol monoester of tallow fatty acids	
Ricebran oil, sulfated, ammonium, potassium, or sodium salt.	
Rosins and rosin derivatives	As provided in § 178.3870 of this chapter.
Silica	
Sodium 2-mercaptobenzothiazole	For use as preservative of defoamer only.
Sodium pentachlorophenate	For use as preservative of defoamer only.

List of substances	Limitations
Sodium trichlorophenate	For use as preservative of defoamer only.
Sperm oil, sulfated, ammonium, potassium, or sodium salt.	
Stearyl alcohol	
Tall oil fatty acids	
Tallow fatty acids, hydrogenated or sulfated	
Tallow, sulfated, ammonium, potassium, or sodium salt.	
Triethanolamine	
Triisopropanolamine	
Waxes, petroleum	

(e) The defoaming agents are used as follows:

(1) The quantity of defoaming agent or agents used shall not exceed the amount reasonably required to accomplish the intended effect, which is to prevent or control the formation of foam.

(2) The defoaming agents are used in the preparation and application of coatings for paper and paperboard.

§ 176.210 Defoaming agents used in the manufacture of paper and paperboard.

Defoaming agents may be safely used in the manufacture of paper and paperboard intended for use in packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) The defoaming agents are prepared from one or more of the substances named in paragraph (d) of this section, subject to any prescribed limitations.

(b) The defoaming agents are used to prevent or control the formation of foam during the manufacture of paper and paperboard prior to and during the sheet-forming process.

(c) The quantity of defoaming agent or agents added during the manufacturing process shall not exceed the amount necessary to accomplish the intended technical effect.

(d) Substances permitted to be used in the formulation of defoaming agents include substances subject to prior sanctions or approval for such use and employed subject to the conditions of such sanctions or approvals, substances generally recognized as safe for use in food, substances generally recognized as safe for use in paper and paperboard, and substances listed in this paragraph, subject to the limitations, if any, prescribed.

(1) Fatty triglycerides, and the fatty acids, alcohols, and dimers derived therefrom:

Beef tallow.	Mustardseed oil.
Castor oil.	Palm oil.
Coconut oil.	Peanut oil.
Corn oil.	Rapeseed oil.
Cottonseed oil.	Ricebran oil.
Fish oil.	Soybean oil.
Lard oil.	Sperm oil.
Linseed oil.	Tall oil.

(2) Fatty triglycerides, and marine oils, and the fatty acids and alcohols derived therefrom (paragraph (d)(1) of this section) reacted with one or more of the following, with or without dehydration, to form chemicals of the category indicated in parentheses:

Aluminum hydroxide (soaps).
Ammonia (amides).
Butanol (esters).
Butoxy-polyoxypropylene, molecular weight 1,000–2,500 (esters).
Butylene glycol (esters).
Calcium hydroxide (soaps).
Diethanolamine (amides).
Diethylene glycol (esters).
Ethylene glycol (esters).
Ethylene oxide (esters and ethers).
Glycerin (mono- and diglycerides).
Hydrogen (hydrogenated compounds).
Hydrogen (amines).
Isobutanol (esters).
Isopropanol (esters).
Magnesium hydroxide (soaps).
Methanol (esters).
Morpholine (soaps).
Oxygen (air-blown oils).
Pentaerythritol (esters).
Polyoxyethylene, molecular weights 200, 300, 400, 600, 700, 1,000, 1,540, 1,580, 1,760, 4,600 (esters).
Polyoxypropylene, molecular weight 200–2,000 (esters).
Potassium hydroxide (soaps).
Propanol (esters).
Propylene glycol (esters).
Propylene oxide (esters).
Sodium hydroxide (soaps).
Sorbitol (esters).
Sulfuric acid (sulfated and sulfonated compounds).
Triethanolamine (amides and soaps).
Triisopropanolamine (amides and soaps).
Trimethylolethane (esters).
Zinc hydroxide (soaps).

(3) Miscellaneous:

Alcohols and ketone alcohols mixture (still-bottom product from C_{12}–C_{15} alcohol manufacturing process).
Amyl alcohol.
Butoxy polyethylene polypropylene glycol molecular weight 900–4,200.
Butoxy-polyoxypropylene molecular weight 1,000–2,500.
Butylated hydroxyanisole.
Butylated hydroxytoluene.
Calcium lignin sulfonate.
Capryl alcohol.
p-Chlorometacresol.
Cyclohexanol.
Diacetyltartaric acid ester of tallow monoglyceride.
Diethanolamine.
Diethylene triamine.
Di-(2-ethylhexyl) phthalate.
2,6-Dimethyl heptanol-4 (nonyl alcohol).
Dimethylpolysiloxane.
Di-*tert*-butyl hydroquinone.
Dodecylbenzene sulfonic acids.
Ethanol.
2-Ethylhexanol.
Ethylenediamine tetraacetic acid tetrasodium salt.
Formaldehyde.
Heavy oxo-fraction (a still-bottom product of iso-octyl alcohol manufacture, of approximate composition: Octyl alcohol 5 percent nonyl alcohol 10 percent, decyl and higher alcohols 35 percent, esters 45 percent, and soaps 5 percent).
2-Heptadecenyl-4-methyl-4-hydroxymethyl-2-oxazoline.
Hexylene glycol (2-methyl-2-4-pentanediol).
12-Hydroxystearic acid.
Isobutanol.
Isopropanol.
Isopropylamine salt of dodecylbenzene sulfonic acid.
Kersosine.
Lanolin.
Methanol.
Methyl 12-hydroxystearate.
Methyl taurine-oleic acid condensate, molecular weight 486.
α,α' - [Methylenebis[4 - (1,1,3,3-tetramethylbutyl) - *o* - phenylene]]*bis*[*omega* - hydroxypoly (oxyethylene)] having 6–7.5 moles of ethylene oxide per hydroxyl group.
Mineral oil.
Mono-, di-, and triisopropanolamine.
Mono- and diisopropanolamine stearate.
Monobutyl ether of ethylene glycol.
Monoethanolamine.
Morpholine.
Myristyl alcohol.
Naphtha.
β-Naphthol.
Nonylphenol.
Odorless light petroleum hydrocarbons.
Oleyl alcohol.
Petrolatum.
o-Phenylphenol.
Pine oil.
Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b) of this chapter.
Polyethylene.
Polyethylene, oxidized (air-blown).
Polymer derived from N-vinyl pyrrolidone combined during its polymerization with copolymers derived from the mixed alkyl (C_{12}—C_{15}, C_{16}, C_{18}, C_{20}, and C_{22}) methacrylate esters and butyl methacrylate; the combined polymer contains no more than 5 weight percent of polymer units derived from N-vinyl pyrrolidone and is present at a level not to exceed 7 parts per million by weight of the finished dry paper and paperboard fibers.
Polyoxyethylene (4 mols) decyl phosphate.
Polyoxyethylene (4 mols) di(2-ethyl hexanoate).
Polyoxyethylene (15 mols) ester of rosin.
Polyoxyethylene (3–15 mols) tridecyl alcohol.
Polyoxypropylene, molecular weight 200–2,000.
Polyoxypropylene-polyoxethylene condensate, minimum molecular weight 950.
Polyoxypropylene-ethylene oxide condensate of ethylene diamine, molecular weight 1,700–3,800.
Polyvinyl pyrrolidone, molecular weight 40,000.
Potassium distearyl phosphate.
Potassium pentachlorophenate.
Potassium trichlorophenate.
Rosins and rosin derivatives identified in § 175.105(c)(5) of this chapter.
Silica.
Sodium alkyl (C_9–C_{15}) benzene-sulfonate.
Sodium dioctyl sulfosuccinate.
Sodium distearyl phosphate.
Sodium lauryl sulfate.
Sodium lignin sulfonate.
Sodium 2-mercaptobenzothiazole.
Sodium naphthalenesulfonic acid (3 mols) condensed with formaldehyde (2 mols).
Sodium orthophenylphenate.
Sodium pentachlorophenate.
Sodium petroleum sulfonate, molecular weight 440–450.
Sodium trichlorophenate.
Stearyl alcohol.
α-[*p*-(1,1,3,3-Tetramethylbutyl)phenyl-, *p*-nonylphenyl-, or *p*-dodecylphenyl]-*omega*-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p*-alkylphenol (alkyl group is 1,1,3,3-tetramethylbutyl, a propylene trimer isomer, or a propylene tetramer isomer) with an average of 1.5–15 moles of ethylene oxide.

Tetrahydrofurfuryl alcohol.
Tributoxyethyl phosphate.
Tributyl phosphate.
Tridecyl alcohol.
Triethanolamine.
Triethylene glycol di(2-ethyl hexanoate).
Tri- (2-ethylhexyl) phosphate.
Tristearyl phosphate.
Wax, petroleum, Type I and Type II.
Wax, petroleum (oxidized).
Wax (montan).

§ 176.230 3,5-Dimethyl-1,3,5,2*H*-tetrahydrothiadiazine-2-thione.

3,5 - Dimethyl - 1,3,5,2*H* - tetrahydrothiadiazine-2-thione may safely be used as a preservative in the manufacture and coating of paper and paperboard intended for use in contact with food in accordance with the following prescribed conditions:

(a) It is used as follows:

(1) In the manufacture of paper and paperboard as a preservative for substances added to the pulp suspension prior to the sheet-forming operation provided that the preservative is volatilized by heat in the drying and finishing of the paper and paperboard.

(2) As a preservative for coatings for paper and paperboard, *Provided*, That the preservative is volatilized by heat in the drying and finishing of the coated paper or paperboard.

(b) The quantity used shall not exceed the least amount reasonably required to accomplish the intended technical effect and shall not be intended to nor, in fact, accomplish any physical or technical effect in the food itself.

(c) The use of a preservative in any substance or article subject to any regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter must comply with any specifications and limitations prescribed by such regulation for the substance or article.

§ 176.250 Poly-1,4,7,10,13-pentaaza-15-hydroxyhexadecane.

Poly - 1,4,7,10,13 - pentaaza - 15 - hydroxyhexadecane may be safely used as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard intended for use in contact with food in an amount not to exceed that necessary to accomplish the intended physical or technical effect and not to exceed 6 pounds per ton of finished paper or paperboard.

§ 176.260 Pulp from reclaimed fiber.

(a) Pulp from reclaimed fiber may be safely used as a component of articles used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of paragraph (b) of this section.

(b) Pulp from reclaimed fiber is prepared from the paper and paperboard products described in paragraph (b) (1) and (2) of this section, by repulping with water to recover the fiber with the least possible amount of nonfibrous substances.

(1) Industrial waste from the manufacture of paper and paperboard products excluding that which bears or contains any poisonous or deleterious substance which is retained in the recovered pulp and that migrates to the food, except as provided in regulations promulgated under sections 406 and 409 of the Federal Food, Drug, and Cosmetic Act.

(2) Salvage from used paper and paperboard excluding that which (i) bears or contains any poisonous or deleterious substance which is retained in the recovered pulp and that migrates to the food, except as provided in regulations promulgated under sections 406 and 409 of the act or (ii) has been used for shipping or handling any such substance.

§ 176.300 Slimicides.

(a) Slimicides may be safely used in the manufacture of paper and paperboard that contact food, in accordance with the following prescribed conditions:

(1) Slimicides are used as antimicrobial agents to control slime in the manufacture of paper and paperboard.

(2) Subject to any prescribed limitations, slimicides are prepared from one or more of the slime-control substances named in paragraph (c) of this section to which may be added optional adjuvant substances as provided for under paragraph (d) of this section.

(3) Slimicides are added to the process water used in the production of paper or paperboard, and the quantity added shall not exceed the amount necessary to accomplish the intended technical effect.

(b) To insure safe usage, the label or labeling of slimicides shall bear adequate directions for use.

(c) Slime-control substances permitted for use in the preparation of slimicides include substances subject to prior sanction or approval for such use and the following:

List of substances	*Limitations*
Acrolein	
Alkenyl (C_{16}–C_{18}) dimethylethyl-ammonium bromide	
n-Alkyl(C_{12}–C_{18}) dimethyl benzyl ammonium chloride	
1,2-benzisothiazolin-3-one	At a level of 0.06 pound per ton of dry weight fiber.
Bis(1,4-bromoacetoxy)-2-butene	
5,5-Bis(bromoacetoxymethyl) *m*-dioxane	
2,6-Bis(dimethylaminomethyl) cyclohexanone	
1,2-Bis(monobromoacetoxy) ethane [CA Reg. No. 3785-34-0].	At a maximum level of 0.10 pound per ton of dry weight fiber.
Bis(trichloromethyl)sulfone	
4-Bromoacetoxymethyl-*m*-dioxolane	
2-Bromo-4'-hydroxyacetophenone	
β-Bromo-*β*-nitrostyrene	At a maximum level of 1 pound per ton of dry weight fiber.
Chloroethyle nebisthiocyanate	
Chlorinated levulinic acids	
Chloromethyl butanethiolsulfonate	
Cupric nitrate	
n-Dialkyl(C_{12}–C_{18})benzylmethylammonium chloride	
2,2-Dibromo-3-nitrilopion-amide	At a maximum level of 0.1 lb/ton of dry weight fiber
2,3-Dibromopropionaldehyde	
3,5-Dimethyl 1,3,5,2*H*-tetrahydrothiadiazine-2-thione	
Dipotassium and disodium ethylenebis(dithiocarbamate)	
Disodium cyanodithioimidocarbonate	
2-Hydroxypropyl methanethiol sulfonate	
2-Mercaptobenzothiazole	
Methylenebisbutanethiolsulfonate	
Methylenebisthiocyanate	
2-Nitrobutyl bromoacetate [CA Reg. No. 3815-06-6]	At a maximum level of 0.15 pound per ton of dry weight fiber.
N-[*α*-(Nitroethyl)benzyl] ethylenediamine	
Potassium 2-mercaptobenzothiazole	
Potassium *N*-hydroxymethyl-*N*-methyldithiocarbamate	
Potassium *N*-methyldithiocarbamate	
Potassium pentachlorophenate	
Potassium trichlorophenate	
Silver fluoride	Limit of addition to process water not to exceed 0.024 pound, calculated as silver fluoride, per ton of paper produced.
Silver nitrate	
Sodium dimethyldithiocarbamate	
Sodium 2-mercaptobenzothiazole	
Sodium pentachlorophenate	
Sodium trichlorophenate	
1,3,6,8-Tetraazatricyclo[6.2.1.1^{3,6}] dodecane	
3,3,4,4-Tetrachlorotetra hydrothiophene 1,1-dioxide	
2-(Thiocyanomethylthio) benzothiazole	
Vinylens bisthiocyanate	

(d) Adjuvant substances permitted to be used in the preparation of slimicides include substances generally recognized as safe for use in food, substances generally recognized as safe for use in paper and paperboard, substances permitted to be used in paper and paperboard by other regulations in this chapter, and the following:

Acetone.
Butlylene oxide.
Dibutyl phthalate.
Didecyl phthalate.
N,N-Dimethylformamide.
Dodecyl phthalate.
Ethanolamine.
Ethylene glycol.
Ethylenediamine.
α,α' - [Methylenebis[4 - (1,1,3,3 - tetramethylbutyl) -*o*-phenylene]] *bis*[*omega*-hydroxypoly (oxyethylene)] having 6–7.5 moles of ethylene oxide per hydroxyl group.
Monomethyl ethers of mono-, di-, and tripropylene glycol.
Nonylphenol reaction product with 9 to 12 molecules of ethylene oxide.
Octylphenol reaction product with 25 molecules of propylene oxide and 40 molecules of ethylene oxide.

§ 176.320 Sodium nitrate-urea complex.

Sodium nitrate-urea complex may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or

holding food, subject to the provisions of this section.

(a) Sodium nitrate-urea complex is a clathrate of approximately two parts urea and one part sodium nitrate.

(b) Sodium nitrate-urea complex conforming to the limitations prescribed in paragraph (b)(1) of this section is used as provided in paragraph (b)(2) of this section.

(1) *Limitations.* (i) It is used as a plasticizer in glassine and greaseproof paper.

(ii) The amount used does not exceed that required to accomplish its intended technical effect or exceed 15 percent by weight of the finshed paper.

(2) *Conditions of use.* The glassine and greaseproof papers are used for packaging dry food or as the food-contact surface for dry food.

§ 176.350 Tamarind seed kernel powder.

Tamarind seed kernel powder may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) Tamarind seed kernel powder is the ground kernel of tamarind seed (*Tamarindus indica* L.) after removal of the seed coat.

(b) It is used in the manufacture of paper and paperboard.

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

Subpart A—[Reserved]

Subpart B—Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces

Sec.

177.1010 Acrylic and modified acrylic plastics, semirigid and rigid.
177.1020 Acrylonitrile/ butadiene / styrene copolymer.
177.1030 Acrylonitrile/butadiene / styrene/ methyl methacrylate copolymer.
177.1040 Acrylonitrile/styrene copolymer.
177.1050 Acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer.
177.1200 Cellophane.
177.1210 Closures with sealing gaskets for food containers.
177.1240 1,4-Cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate copolymer.
177.1310 Ethylene-acrylic acid copolymers.
177.1320 Ethylene-ethyl acrylate copolymers.
177.1330 Ethylene-methacrylic acid copolymers, ethylene-methacrylic acid-vinyl acetate copolymers, and their partial salts.
177.1340 Ethylene-methyl acrylate copolymer resins.
177.1350 Ethylene-vinyl acetate copolymers.
177.1360 Ethylene-vinyl acetate-vinyl alcohol copolymers.
177.1380 Fluorocarbon resins.
177.1400 Hydroxyethyl cellulose film, water-insoluble.
177.1420 Isobutylene polymers.
177.1430 Isobutylene-butene copolymers.
177.1440 4,4'-Isopropylidenediphenol - epichlorohydrin resins minimum molecular weight 10,000.
177.1460 Melamine-formaldehyde resins in molded articles.
177.1480 Nitrile rubber modified acrylonitrile-methyl acrylate copolymers.
177.1500 Nylon resins.
177.1520 Olefin polymers.
177.1550 Perfluorocarbon resins.
177.1570 Poly-1-butene resins and butene/ethylene copolymers.
177.1580 Polycarbonate resins.
177.1590 Polyester elastomers.
177.1600 Polyethylene resins, carboxyl modified.
177.1610 Polyethylene, chlorinated.
177.1620 Polyethylene, oxidized.
177.1630 Polyethylene phthalate polymers.
177.1640 Polystyrene and rubber-modified polystyrene.
177.1650 Polysulfide polymer-polyepoxy resins.
177.1660 Poly(tetramethylene terephthalate).
177.1670 Polyvinyl alcohol film.
177.1680 Polyurethane resins.
177.1810 Styrene block polymers.
177.1820 Styrene-maleic anhydride copolymers.
177.1830 Styrene-methyl methacrylate copolymers.
177.1850 Textryls.
177.1900 Urea-formaldehyde resins in molded articles.
177.1950 Vinyl chloride-ethylene copolymers.
177.1960 Vinyl chloride-hexene-1 copolymers.
177.1970 Vinyl chloride-lauryl vinyl ether copolymers.
177.1980 Vinyl chloride-propylene copolymers.

Subpart C—Substances for Use Only as Components of Articles Intended for Repeated Use

177.2210 Ethylene polymer, chlorosulfonated.
177.2250 Filters, microporous polymeric.
177.2260 Filters, resin-bonded.
177.2280 4,4'-Isopropylidenediphenol - epichlorohydrin thermosetting epoxy resins.
177.2410 Phenolic resins in molded articles.
177.2420 Polyester resins, cross-linked.
177.2430 Polyether resins, chlorinated.
177.2450 Polyamide-imide resins.
177.2460 Poly(2,6 - dimethyl-1,4-phenylene) oxide resins.
177.2470 Polyoxymethylene copolymer.
177.2480 Polyoxymethylene homopolymer.
177.2490 Polyphenylene sulfide resins.
177.2500 Polysulfone resins.
177.2510 Polyvinylidene fluoride resins.
177.2600 Rubber articles intended for repeated use.
177.2710 Styrene-divinylbenzene resins, cross-linked.
177.2800 Textiles and textile fibers.
177.2910 Ultra-filtration membranes.

AUTHORITY: Secs. 409, 701, 52 Stat. 1055–1056 as amended, 72 Stat. 1785–1788 as amended (21 U.S.C. 348, 371), unless otherwise noted.

Subpart A—[Reserved]

Subpart B—Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces

§ 177.1010 Acrylic and modified acrylic plastics, semirigid and rigid.

Semirigid and rigid acrylic and modified acrylic plastics may be safely used as articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) The optional substances used in the formulation of the semirigid and rigid acrylic and modified acrylic plastics include substances generally recognized as safe in food, substance used in accordance with a prior sanction or approval, substances permitted for use in such plastics by regulations in Parts 170 through 189 of this chapter, and substances identified in this paragraph. At least 50 weight-percent of the polymer content of the finished plastics shall consist of polymer units derived from one or more of the acrylic or methacrylic monomers listed in paragraph (a)(1) of this section.

(1) Homopolymers and copolymers of the following monomers:

n-Butyl acrylate.
n-Butyl methacrylate.
Ethyl acrylate.
2-Ethylhexyl acrylate.
Ethyl methacrylate.
Methyl acrylate.
Methyl methacrylate.

(2) Copolymers produced by copolymerizing one or more of the monomers listed in paragraph (a)(1) of this section with one or more of the following monomers:

Acrylonitrile.
Methacrylonitrile.
α-Methylstyrene.
Styrene.
Vinyl chloride.
Vinylidene chloride.

(3) Polymers identified in paragraph (a)(1) and (2) of this section containing no more than 5 weight-percent of total polymer units derived by copolymerization with one or more of the monomers listed in paragraph (a)(3)(i) and (ii) of this section. Monomers listed in paragraph (a)(3)(ii) of this section are limited to use only in plastic articles intended for repeated use in contact with food.

(i) List of minor monomers:

Acrylamide.
Acrylic acid.
1,3-Butylene glycol dimethacrylate.
1,4-Butylene glycol dimethacrylate.
Diethylene glycol dimethacrylate.
Dipropylene glycol dimethacrylate.
Divinylbenzene.
Ethylene glycol dimethacrylate.
Itaconic acid.
Methacrylic acid.
N-Methylolacrylamide.
N-Methylolmethacrylamide.
4-Methyl-1,4-pentanediol dimethacrylate.
Propylene glycol dimethacrylate.
Trivinylbenzene.

(ii) List of minor monomers limited to use only in plastic articles intended for repeated use in contact with food:

tert-Butyl acrylate.
tert-Butylaminoethyl methacrylate.
sec-Butyl methacrylate.
tert-Butyl methacrylate.
Cyclohexyl methacrylate.
Dimethylaminoethyl methacrylate.
2-Ethylhexyl methacrylate.
Hydroxyethyl methacrylate.
Hydroxyethyl vinyl sulfide.
Hydroxypropyl methacrylate.
Isobornyl methacrylate.
Isobutyl methacrylate.
Isopropyl acrylate.
Isopropyl methacrylate.
Methacrylamide.
Methacrylamidoethylene urea.
Methacryloxyacetamidoethylethylene urea.
Methacryloxyacetic acid.

n-Propyl methacrylate.
3,5,5-Trimethylcyclohexyl methacrylate.

(4) Polymers identified in paragraph (a)(1), (2), and (3) of this section are mixed together and/or with the following polymers, provided that no chemical reactions, other than addition reactions, occur when they are mixed:

Butadiene-acrylonitrile copolymers.
Butadiene-acrylonitrile-styrene copolymers.
Butadiene - acrylonitrile - styrene - methyl methacrylic copolymers.
Butadiene-styrene copolymers.
Butyl rubber
Natural rubber.
Polybutadiene.
Poly (3-chloro-1,3-butadiene).
Polyesters identified in § 175.300(b) (3) (vii) of this chapter.
Polyvinyl chloride.
Vinyl chloride copolymers complying with § 177.1980.
Vinyl chloride-vinyl acetate copolymers.

(5) Antioxidants and stabilizers identified in § 175.300(b)(3)(xxx) of this chapter and the following:

Di-*tert*-butyl-*p*-cresol.
2-Hydroxy-4-methoxybenzophenone.
2 - Hydroxy - 4 - methoxy - 2 - carboxybenzophenone.
3-Hydroxyphenyl benzoate.
p-Methoxyphenol.
Methyl salicylate.
Octadecyl 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate: For use only at levels not exceeding 0.01 percent by weight in rigid acrylic and modified acrylic plastics intended for repeated food-contact use.
Phenyl salicylate.

(6) Release agents: Fatty acids derived from animal and vegetable fats and oils, and fatty alcohols derived from such acids.

(7) Surface active agent: Sodium dodecylbenzenesulfonate.

(8) Miscellaneous materials:

Di(2-ethylhexyl) phthalate, for use only as a flow promoter at a level not to exceed 3 weight-percent based on the monomers.
Dimethyl phthalate.
Oxalic acid, for use only as a polymerization catalyst aid.
Tetraethylenepentamine, for use only as a catalyst activator at a level not to exceed 0.5 weight-percent based on the monomers.
Toluene.
Xylene.

(b) The semirigid and rigid acrylic and modified acrylic plastics, in the finished form in which they are to contact food, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature as determined from tables 1 and 2 of § 176.170(c) of this chapter, shall yield extractives not to exceed the following, when tested by the methods prescribed in paragraph (c) of this section:

(1) Total nonvolatile extractives not to exceed 0.3 milligram per square inch of surface tested.

(2) Potassium permanganate oxidizable distilled water and 8 and 50 percent alcohol extractives not to exceed an absorbance of 0.15.

(3) Ultraviolet-absorbing distilled water and 8 and 50 percent alcohol extractives not to exceed an absorbance of 0.30.

(4) Ultraviolet-absorbing *n*-heptane extractives not to exceed an absorbance of 0.10.

(c) *Analytical methods*—(1) *Selection of extractability conditions.* These are to be chosen as provided in § 176.170 (c) of this chapter.

(2) *Preparation of samples.* Sufficient samples to allow duplicates of all applicable tests shall be cut from the articles or formed from the plastic composition under tests, as strips about 2.5 inches by about 0.85-inch wide by about 0.125-inch thick. The total exposed surface should be 5 square inches ±0.5-square inch. The samples, after preparation, shall be washed with a clean brush under hot tapwater, rinsed under running hot tapwater (140° F minimum), rinsed with distilled water, and air-dried in a dust-free area or in a desiccator.

(3) *Preparation of solvents.* The water used shall be double-distilled water, prepared in a still using a block tin condenser. The 8 and 50 percent (by volume) alcohol solvents shall be prepared from ethyl alcohol meeting the specifications of U.S.P. XVII and diluted with double-distilled water that has been prepared in a still using a tin block condenser. The *n*-heptane shall be spectrophotometric grade. Adequate precautions must be taken to keep all solvents dust-free.

(4) *Blank values on solvents.* (i) Duplicate determinations of residual solids shall be run on samples of each solvent that have been exposed to the temperature-time conditions of the extraction test without the plastic sample. Sixty milliliters of exposed solvent is pipetted into a clean, weighed platinum dish, evaporated to 2–5 milliliters on a nonsparking, low-temperature hot plate and dried in 212° F oven for 30 minutes. The residue for each solvent shall be determined by weight and the average residue weight used as the blank value in the total solids determination set out in paragraph (c) of this section. The residue for an acceptable solvent sample shall not exceed 0.5 milligram per 60 milliliters.

(ii) For acceptability in the ultraviolet absorbers test, a sample of each solvent shall be scanned in an ultraviolet spectrophotometer in 5-centimeter silica spectrophotometric absorption cells. The absorbance of the distilled water when measured versus air in the reference cell shall not exceed 0.03 at any point in the wavelength region of 245 to 310 mμ. The absorbance of the 8 percent alcohol when measured versus distilled water in the reference cell shall not exceed 0.01 at any point in the wavelength region of 245 to 310 mμ. The absorbance of the 50 percent alcohol when measured versus distilled water in the reference cell shall not exceed 0.05 at any point in the wavelength region of 245 to 310 mμ. The absorbance of the heptane when measured versus distilled water in the reference cell shall not exceed 0.15 at 245, 0.09 at 260, 0.04 at 270, and 0.02 at any point in the wavelength region of 280 to 310 mμ.

(iii) Duplicate ultraviolet blank determinations shall be run on samples of each solvent that have been exposed to the temperature-time conditions of the extraction test without the plastic sample. An aliquot of the exposed solvent shall be measured versus the unexposed solvent in the reference cell. The average difference in the absorbances at any wavelength in the region of 245 to 310 mμ shall be used as a blank correction for the ultraviolet absorbers measured at the same wavelength according to paragraph (c)(8)(ii) of this section.

(iv) The acceptability of the solvents for use in the permanganate test shall be determined by preparing duplicate permanganate test blanks according to paragraph (c)(7)(iv) of this section. For this test, the directions referring to the sample extract shall be disregarded. The blanks shall be scanned in 5-centimeter silica spectrophotometric cells in the spectrophotometer versus the appropriate solvent as reference. The absorbance in distilled water in the wavelength region of 544 to 552 mμ should be 1.16 but must not be less than 1.05 nor more than 1.25. The absorbance in the 8 and 50 percent alcohol must not be less than 0.85 nor more than 1.15.

(v) Duplicate permanganate test determinations shall be run on samples of distilled water and 8 and 50 percent alcohol solvents that have been exposed to the temperature-time conditions of the extraction test without the plastic sample. The procedure shall be as described in paragraph (c)(7)(iv) of this section, except that the appropriate exposed solvent shall be substituted where the directions call for sample extract. The average difference in the absorbances in the region of 544 to 552 mμ shall be used as a blank correction for the determination of permanganate oxidizable extractives according to paragraph (c)(7)(iv) of this section.

(5) *Extraction procedure.* For each extraction, place a plastic sample in a clean 25 millimeters x 200 millimeters hard-glass test tube and add solvent equal to 10 milliliters of solvent per square inch of plastic surface. This amount will be between 45 milliliters and 55 milliliters. The solvent must be preequilibrated to the temperature of the extraction test. Close the test tube with a ground-glass stopper and expose to the specified temperature for the specified time. Cool the tube and contents to room temperature if necessary.

(6) *Determination of total nonvolatile extractives.* Remove the plastic strip from the solvent with a pair of clean forceps and wash the strip with 5 milliliters of the appropriate solvent, adding the washings to the contents of the test tube. Pour the contents of the test tube into a clean, weighed platinum dish.

Wash the tube with 5 milliliters of the appropriate solvent and add the solvent to the platinum dish. Evaporate the solvent to 2–5 milliliters on a nonsparking, low-temperature hotplate. Complete the evaporation in a 212° F oven for 30 minutes. Cool the dish in a desiccator for 30 minutes and weigh to the nearest 0.1 milligram. Calculate the total nonvolatile extractives as follows:

$$\text{Milligrams extractives per square inch} = \frac{e-b}{s};$$

$$\text{Extractives in parts per million} = \left(\frac{e}{s}-\frac{b}{s}\right)(100),$$

where:
e = Total increase in weight of the dish, in milligrams.
b = Blank value of the solvent in milligrams, as determined in paragraph (c)(4)(i) of this section.
s = Total surface of the plastic sample in square inches.

(7) *Determination of potassium permanganate oxidizable extractives.* (i) Pipette 25 milliliters of distilled water into a clean 125-milliliter Erlenmeyer flask that has been rinsed several times with aliquots of distilled water. This is the blank. Prepare a distilled water solution containing 1.0 part per million of *p*-methoxyphenol (melting point 54–56° C, Eastman grade or equivalent). Pipette 25 milliliters of this *p*-methoxyphenol solution into a rinsed Erlenmeyer flask. Pipette exactly 3.0 milliliters of 154 parts per million aqueous potassium permanganate solution into the *p*-methoxyphenol and exactly 3.0 milliliters into the blank, in that order. Swirl both flasks to mix the contents and then transfer aliquots from each flask into matched 5-centimeter spectrophotometric absorption cells. The cells are placed in the spectrophotometer cell compartment with the *p*-methoxyphenol solution in the reference beam. Spectrophotometric measurement is conducted as in paragraph (c)(7)(iv) of this section. The absorbance reading in the region 544–552 mμ should be 0.24 but must be not less than 0.12 nor more than 0.36. This test shall be run in duplicate. For the purpose of ascertaining compliance with the limitations in paragraph (b)(2) of this section, the absorbance measurements obtained on the distilled water extracts according to paragraph (c)(7)(iv) of this section shall be multiplied by a correction factor, calculated as follows:

$$\frac{0.24}{\text{Average of duplicate } p\text{-methoxyphenol absorbance determinations according to this paragraph (c)(7)(i) of this section.}} = \text{Correction factor for water extracts.}$$

(ii) The procedure in paragraph (c)(7)(i) of this section is repeated except that, in this instance, the solvent shall be 8 percent alcohol. The absorbance in the region 544–552 mμ should be 0.26 but must be not less than 0.13 nor more than 0.39. This test shall be run in duplicate. For the purpose of ascertaining compliance with the limitations prescribed in paragraph (b)(2) of this section, the absorbance measurements obtained on the 8 percent alcohol extracts according to paragraph (c)(7)(iv) of this section shall be multiplied by a correction factor, calculated as follows:

$$\frac{0.26}{\text{Average of duplicate } p\text{-methoxyphenol absorbance determination according to this paragraph (c)(7)(ii) of this section.}} = \text{Correction factor for aqueous 8 percent alcohol extracts.}$$

(iii) The procedure in paragraph (c)(7)(i) of this section is repeated except that, in this instance, the solvent shall be 50 percent alcohol. The absorbance in the region 544–552 mμ should be 0.25 but must be not less than 0.12 nor more than 0.38. This test shall be run in duplicate. For the purpose of ascertaining compliance with the limitations prescribed in paragraph (b)(2) of this section, the absorbance measurements obtained on the 50 percent alcohol extracts according to paragraph (c)(7)(iv) of this section shall be multiplied by a correction factor, calculated as follows:

$$\frac{0.25}{\text{Average of duplicate } p\text{-methoxyphenol absorbance determinations according to paragraph (c)(7)(ii) of this section.}} = \text{Correction factor for 50 percent aqueous alcohol extracts.}$$

(iv) *Water and 8 and 50 percent alcohol extracts.* Pipette 25 milliliters of the appropriate solvent into a clean, 125-milliliter Erlenmeyer flask that has been rinsed several times with aliquots of the same solvent. This is the blank. Into another similarly rinsed flask, pipette 25 milliliters of the sample extract that has been exposed under the conditions specified in paragraph (c)(5) of this section. Pipette exactly 3.0 milliliters of 154 parts per million aqueous potassium permanganate solution into the sample and exactly 3.0 milliliters into the blank, in

that order. Before use, the potassium permanganate solution shall be checked as in paragraph (c)(7)(i) of this section. Both flasks are swirled to mix the contents, and then aliquots from each flask are transferred to matched 5-centimeter spectrophotometric absorption cells. Both cells are placed in the spectrophotometer cell compartment with the sample solution in the reference beam. The spectrophotometer is adjusted for 0 and 100 percent transmittance at 700 mu. The spectrum is scanned on the absorbance scale from 700 mμ to 500 mμ in such a way that the region 544 mμ to 552 mμ is scanned within 5 minutes to 10 minutes of the time that permanganate was added to the solutions. The height of the absorbance peak shall be measured, corrected for the blank as determined in paragraph (c)(4)(v) of this section, and multiplied by the appropriate correction factor determined according to paragraph (c)(7)(i), (ii), and (iii) of this section. This test shall be run in duplicate and the two results averaged.

(8) *Determination of ultraviolet-absorbing extractives.* (i) A distilled water solution containing 1.0 part per million of *p*-methoxyphenol (melting point 54° C.–56° C. Eastman grade or equivalent) shall be scanned in the region 360 to 220 mμ in 5-centimeter silica spectrophotometric absorption cells versus a distilled water reference. The absorbance at the wavelength of maximum absorbance (should be about 285 mμ) is about 0.11 but must be not less than 0.08 nor more than 0.14. This test shall be run in duplicate. For the purpose of ascertaining compliance with the limitations prescribed in paragraph (b)(3) and (4) of this section, the absorbance obtained on the extracts according to paragraph (c)(8)(ii) of this section shall be multiplied by a correction factor, calculated as follows:

$$\frac{0.11}{\text{Average of duplicate } p\text{-methoxyphenol absorbance determinations according to this paragraph (c)(8)(i) of this section.}} = \text{Correction factor for ultraviolet absorbers test.}$$

(ii) An aliquot of the extract that has been exposed under the conditions specified in paragraph (c)(5) of this section is scanned in the wavelength region 360 to 220 mμ versus the appropriate solvent reference in matched 5-centimeter silica spectrophotometric absorption cells. The height of any absorption peak shall be measured, corrected for the blank as determined in paragraph (c)(4)(iii) of this section, and multiplied by the correction factor determined according to paragraph (c)(8)(i) of this section.

(d) In accordance with good manufacturing practice, finished semirigid and rigid acrylic and modified acrylic plastics intended for repeated use in contact with food shall be thoroughly cleansed prior to their first use in contact with food.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

§ 177.1020 Acrylonitrile/butadiene/styrene copolymer.

Acrylonitrile/butadiene/styrene copolymer identified in this section may be safely used as an article or component of articles intended for use with all foods, except those containing alcohol, under conditions of use E, F, and G described in table 2 of § 176.170(c) of this chapter.

(a) *Identity.* For the purpose of this section, the acrylonitrile/butadiene/styrene copolymer consists of:

(1) Eighty-four to eighty-nine parts by weight of a matrix polymer containing 73 to 78 parts by weight of acrylonitrile and 22 to 27 parts by weight of styrene; and

(2) Eleven to sixteen parts by weight of a grafted rubber consisting of (i) 8 to 13 parts of butadiene/styrene elastomer containing 72 to 77 parts by weight of butadiene and 23 to 28 parts by weight of styrene and (ii) 3 to 8 parts by weight of a graft polymer having the same composition range as the matrix polymer.

(b) *Adjuvants.* The copolymer identified in paragraph (a) of this section may contain adjuvant substances required in its production. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted in this part, and the following:

Substances	Limitations
2-Mercaptoethanol	The finished copolymer shall contain not more than 100 ppm 2-mercaptoethanol acrylonitrile adduct as determined by a method available upon request from the Commissioner of Food and Drugs.

(c) *Specifications.* (1) Nitrogen content of the copolymer is in the range of 16 to 18.5 percent as determined by Micro-Kjeldahl analysis.

(2) Residual acrylonitrile monomer content of the finished copolymer articles is not more than 11 parts per million as determined by a gas chromatographic method, available upon request from the Commissioner of Food and Drugs.

(d) *Extractive limitations.* (1) Total nonvolatile extractives not to exceed 0.0005 milligram per square inch surface area when the finished food contact article is exposed to distilled water, 3 percent acetic acid, or *n*-heptane for 8 days at 120° F.

(2) The finished food-contact article shall yield not more than 0.0015 milligram per square inch of acrylonitrile monomer when exposed to distilled water and 3 percent acetic acid at 150° F for 15 days when analyzed by a polarographic method, available upon request from the Division of Food and Color Additives, HFF–330, 200 C St., SW., Washington, DC 20204.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 (21 U.S.C. 321(s), 348, 371(a)).)

NOTE: § 177.1020 (formerly § 121.2633) insofar as it permits an acrylonitrile/butadiene/styrene copolymer to be used to fabricate beverage containers, was stayed by an order published in the FEDERAL REGISTER of March 11, 1977 (42 FR 13546).

§ 177.1030 Acrylonitrile/butadiene/styrene/methyl methacrylate copolymer.

Acrylonitrile/butadiene/styrene/methyl methacrylate copolymer identified in this section may be safely used as an article or component of articles intended for use with food identified in table 1 of § 176.170(c) of this chapter as type I, II, III, IVA, IVB, V, VIB, (except bottles intended to hold carbonated beverages), VIIA, VIIB, VIII and IX, under conditions of use C, D, E, F, and G described in table 2 of § 176.170(c) of this chapter with a high temperature limitation of 190° F.

(a) *Identity.* For the purpose of this section, acrylonitrile/butadiene/styrene/methyl methacrylate copolymer consists of: (1) 73 to 79 parts by weight of a matrix polymer containing 64 to 69 parts by weight of acrylonitrile, 25 to 30 parts by weight of styrene and 4 to 6 parts by weight of methyl methacrylate; and (2) 21 to 27 parts by weight of a grafted rubber consisting of (i) 16 to 20 parts of butadiene/styrene/elastomer containing 72 to 77 parts by weight of butadiene and 23 to 28 parts by weight of styrene and (ii) 5 to 10 parts by weight of a graft polymer having the same composition range as the matrix polymer.

(b) *Adjuvants.* The copolymer identified in paragraph (a) of this section may contain adjuvant substances required in its production. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted under applicable regulations in this part, and the following:

Substances	Limitations
2 - Mercaptoethanol	The finished copolymer shall contain not more than 800 ppm 2-mercaptoethanol - acrylonitrile adduct as determined by a method available upon request from the Commissioner of Food and Drugs.

(c) *Specifications.* (1) Nitrogen content of the copolymer is in the range of 13.0 to 16.0 percent as determined by Micro-Kjeldahl analysis.

(2) Residual acrylonitrile monomer content of the finished copolymer articles is not more than 11 parts per million as determined by a gas chromatographic method available upon request from the Food and Drug Administration, Bureau of Foods, Division of Food and Color Ad-

ditives (HFF–330), 200 C St. SW., Washington, DC 20204.

(d) *Extractive limitations.* (1) Total nonvolatile extractives not to exceed 0.0005 milligram per square inch surface area of the food-contact article when exposed to distilled water, 3 percent acetic acid, 50 percent ethanol, and *n*-heptane for 10 days at 120° F.

(2) The finished food-contact article shall yield not more than 0.0025 milligram per square inch of acrylonitrile monomer when exposed to distilled water, 3 percent acetic acid and *n*-heptane at 190° F for 2 hours, cooled to 120° F (80 to 90 minutes) and maintained at 120° F for 10 days when analyzed by a polarographic method available upon request from the Food and Drug Administration, Bureau of Foods, Division of Food and Color Additives (HFF–330), 200 C St., SW., Washington, DC 20204.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

NOTE: § 177.1030 (formerly § 121.2627), insofar as it permits an acrylonitrile/butadiene/styrene/methyl methacrylate copolymer to be used to fabricate beverage containers, was stayed by an order published in the FEDERAL REGISTER of March 11, 1977 (42 FR 13546).

§ 177.1040 Acrylonitrile/styrene copolymer.

Acrylonitrile/styrene copolymers identified in this section may be safely used as a component of packaging materials subject to the provisions of this section.

(a) *Identity.* For the purposes of this section acrylonitrile/styrene copolymers are basic copolymers meeting the specifications prescribed in paragraph (c) of this section.

(b) *Adjuvants.* (1) The copolymers identified in paragraph (c) of this section may contain adjuvant substances required in their production, with the exception that they shall not contain mercaptans or other substances which form reversible complexes with acrylonitrile monomer. Permissible adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted under applicable regulations in this part, and those authorized in paragraph (b) (2) of this section.

(2) The optional adjuvants for the acrylonitrile/styrene copolymer identified in paragraph (c) (1) of this section are as follows:

Substances	*Limitation*
Condensation polymer of toluene sulfonamide and formaldehyde.	0.15 pct maximum.

(c) Specifications.

Acrylonitrile styrene copolymers	Maximum residual acrylonitrile monomer content of finished article	Nitrogen content of copolymer	Maximum extractable fractions at specified temperatures and times	Conformance with certain specifications
1. Acrylonitrile/styrene copolymer consisting of the copolymer produced by polymerization of 66–72 parts by weight of acrylonitrile and 28–34 parts by weight of styrene; for use with food of type VI–B identified in table 1 of sec. 176.170(c) of this chapter under conditions of use C, D, E, F, G described in table 2 of sec. 176.170(c) of this chapter.	80 p/m *.....	17.4 to 19 pct..	Total nonvolatile extractives not to exceed 0.01 mg/in² surface area of the food contact article when exposed to distilled water and 3 pct acetic acid for 10 d at 150° F. The extracted copolymer shall not exceed 0.001 mg/in² surface area of the food contact article when exposed to distilled water and 3 pct acetic acid for 10 d at 150° F.*	Minimum number average molecular weight is 30,000.*
2. Acrylonitrile/styrene copolymer consisting of the copolymer produced by polymerization of 45–65 parts by weight of acrylonitrile and 35–55 parts by weight of styrene; for use with food of types I, II, III, IV, V, VI (except bottles), VII, VIII, and IX identified in table 1 of sec. 176.170(c) of this chapter under conditions B (not to exceed 200° F), C, D, E, F, G described in table 2 of sec. 176.170(c) of this chapter.	50 p/m *.....	12.2 to 17.2 pct..	Extracted copolymer not to exceed 2.0 p.p.m. in aqueous extraction *n*-heptane extract obtained when 100-g sample of the basic copolymer in the form of particles of a size that will pass through a U.S. Standard Sieve No. 6 and that will be held on a U.S. Standard Sieve No. 10 is extracted with 250 ml of deionized water or reagent grade *n*-heptane at reflux temperature for 2h.*	Minimum 10 pct solution viscosity at 25° C is 10 cP.*

*Method available from: Food and Drug Administration, Bureau of Foods, Division of Food and Color Additives (HFF–330), 200 C St. SW., Washington, D.C. 20204.

(d) *Interim listing.* Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

NOTE: § 177.1040 (formerly § 121.2629), insofar as it permits an acrylonitrile/styrene copolymer to be used to fabricate beverage containers, was stayed by an order published in the FEDERAL REGISTER of March 11, 1977 (42 FR 13546).

§ 177.1050 Acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer.

Acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer identified in this section may be safely used as a component of bottles intended for use with foods identified in table I of § 176.170(c) of this chapter as type VI–B under conditions for use E, F, or G described in table 2 of § 176.170(c) of this chapter.

(a) *Identity.* For the purpose of this section, acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer consists of a blend of:

(1) 82–88 parts by weight of a matrix copolymer produced by polymerization of 77–82 parts by weight of acrylonitrile and 18–23 parts of styrene; and

(2) 12–18 parts by weight of a grafted rubber consisting of (i) 8–12 parts of butadiene/styrene elastomer containing 77–82 parts by weight of butadiene and 18–23 parts by weight of styrene and (ii) 4–6 parts by weight of a graft copolymer consisting of 70–77 parts by weight of acrylonitrile and 23–30 parts by weight of styrene.

(b) *Adjuvants.* The modified copolymer identified in paragraph (a) of this section may contain adjuvant substances required in its production. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted under applicable regulations in this part, and the following:

Substances	*Limitations*
n-Dodecylmercaptan	The finished copolymer shall contain not more than 500 parts per million (ppm) dodecylmercaptan as dodecylmercaptopropionitrile as determined by a method available upon request from the Commissioner of Food and Drugs.

(c) *Specifications.* (1) Nitrogen content of the modified copolymer is in the range of 17.7–19.8 percent.

(2) Intrinsic viscosity of the matrix copolymer in butyrolactone is not less than 0.5 deciliter/gram at 35° C, as determined by a method available upon request from the Food and Drug Administration, Bureau of Foods, Division of Food and Color Additives (HFF–330), 200 C St. SW., Washington, D.C. 20204.

(3) Residual acrylonitrile monomer content of the modified copolymer articles is not more than 11 ppm as determined by a gas chromatographic method available upon request from the Commissioner of Food and Drugs.

(d) *Extractives limitations.* The following extractives limitations are determined by an infrared spectrophotometric method, available upon request from the Commissioner of Food and Drugs, and are applicable to the modified copolymers in the form of particles of a size that will pass through a U.S. Standard Sieve No. 6 and that will be held on a U.S. Standard Sieve No. 10:

(1) The extracted copolymer shall not exceed 2.0 ppm in aqueous extract obtained when a 100-gram sample of copolymer is extracted with 250 milliliters of freshly distilled water at reflux temperature for 2 hours.

(2) The extracted coplymer shall not exceed 0.5 ppm in *n*-heptane when a 100-gram sample of the basic copolymer is extracted with 250 milliliters spectral grade *n*-heptane at reflux temperature for 2 hours.

(e) *Accelerated extraction end test.* The modified copolymer shall yield acry-

lonitrile monomer not in excess of 0.4 ppm when tested as follows:

(1) The modified copolymer shall be in the form of eight strips ½ inch by 4 inches by .03 inch.

(2) The modified copolymer strips shall be immersed in 225 milliliters of 3 percent acetic acid in a Pyrex glass pressure bottle.

(3) The pyrex glass pressure bottle is then sealed and heated to 150° F in either a circulating air oven or a thermostat controlled bath for a period of 8 days.

(4) The Pyrex glass pressure bottle is then removed from the oven or bath and cooled to room temperature. A sample of the extracting solvent is then withdrawn and analyzed for acrylonitrile monomer by a gas chromatographic method available upon request from the Commissioner of Food and Drugs.

(f) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

NOTE: § 177.1050 (formerly § 121.2625), insofar as it permits an acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer to be used to fabricate beverage containers, was stayed by an order published in the FEDERAL REGISTER of March 11, 1977 42 FR 13546).

§ 177.1200 Cellophane.

Cellophane may be safely used for packaging food in accordance with the following prescribed conditions:

(a) Cellophane consists of a base sheet made from regenerated cellulose to which have been added certain optional substances of a grade of purity suitable for use in food packaging as constituents of the base sheet or as coatings applied to impart desired technological properties.

(b) Subject to any limitations prescribed in this part, the optional substances used in the base sheet and coating may include:

(1) Substances generally recognized as safe in food.

(2) Substances for which prior approval or sanctions permit their use in cellophane, under conditions specified in such sanctions and substances listed in § 181.22 of this chapter.

(3) Substances that by any regulation promulgated under section 409 of the act may be safely used as components of cellophane.

(4) Substances named in this section and further identified as required.

(c) List of substances:

	Limitations (residue and limits of addition expressed as percent by weight of finished packaging cellophane)
Acrylonitrile-butadiene copolymer resins	As the basic polymer.
Acrylonitrile-butadiene-styrene copolymer resins	Do.
Acrylonitrile-styrene copolymer resins	Do.
Acrylonitrile-vinyl chloride copolymer resins	Do.
N-Acyl sarcosines where the acyl group is lauroyl or stearoyl.	For use only as release agents in coatings at levels not to exceed a total of 0.3 percent by weight of the finished packaging cellophane.
Alkyl ketene dimers identified in §178.120 of this chapter.	
Aluminum hydroxide	
Aluminum silicate	
Ammonium persulfate	
Ammonium sulfate	
Behenamide	
Butadiene-styrene copolymer	As the basic polymer.
1, 3-Butanediol	
n-Butyl acetate	0.1 percent.
n-Butyl alcohol	Do.
Calcium ethyl acetoacetate	
Calcium stearoyl-2-lactylate identified in §172.844 of this chapter.	Not to exceed 0.5 percent weight of cellophane.
Carboxymethyl hydroxyethylcellulose polymer	
Castor oil, hydrogenated	
Castor oil phthalate with adipic acid and fumaric acid-diethylene glycol polyester.	As the basic polymer.
Castor oil phthalate, hydrogenated	Alone or in combination with other phthalates where total phthalates do not exceed 5 percent.
Castor oil, sulfonated, sodium salt	
Cellulose acetate butyrate	
Cellulose acetate propionate	
Cetyl alcohol	
Clay, natural	
Coconut oil fatty acid (C_{12}–C_{18}) diethanolamide, coconut oil fatty acid (C_{12}–C_{18}) diethanolamine soap, and diethanolamine mixture having total alkali (calculated as potassium hydroxide) of 16–18% and having an acid number of 25–35.	For use only as an adjuvant employed during the processing of cellulose pulp used in the manufacture of cellophane base sheet.
Copal resin, heat processed	As basic resin.
Damar resin	
Defoaming agents identified in § 176.200 of this chapter	
Dialkyl ketones where the alkyl groups are lauryl or stearyl.	Not to exceed a total of 0.35 percent.
Dibutylphthalate	Alone or in combination with other phthalates where total phthalates do not exceed 5 percent.
Dicyclohexyl phthalate	Do.
Diethylene glycol ester of the adduct of terpene and maleic anhydride.	
Di(2-ethylhexyl) adipate	Alone or in combination with other phthalates where total phthalates do not exceed 5 percent.
Di(2-ethylhexyl) phthalate	Alone or in combination with other phthalates where total phthalates do not exceed 5 percent.
Diisobutyl phthalate	Do.
Dimethylcyclohexyl phthalate	0.005 percent for use only as a flocculant for slip agents.
Dimethyldialkyl (C_8–C_{18}) ammonium chloride	For use only as a stabilizer at a level not to exceed 0.55 percent by weight of the coating solids in vinylidene chloride copolymer waterproof coatings prepared from vinylidene chloride copolymers identified in this paragraph, provided that such vinylidene chloride copolymers contain not less than 90 percent by weight of polymer units derived from vinylidene chloride.
Di-n-octyltin bis(2-ethylhexyl maleate)	

	Limitations (residue and limits of addition expressed as percent by weight of finished packaging cellophane)
N,N'-Dioleoylethylenediamine, *N,N'*-dilinoleoylethylenediamine, and *N*-oleoyl-*N'*-linoleoylethylene-diamine mixture produced when tall oil fatty acids are made to react with ethylenediamine such that the finished mixture has a melting point of 212°–228° F. as determined by ASTM Method D 127–60, and an acid value of 10 maximum.	0.5 percent.
N,N'-Dioleoylethylenediamine (*N,N'*-ethylenebisoleamide).	
Disodium EDTA	
Distearic acid ester of di(hydroxyethyl)diethylenetriamine monoacetate.	0.06 percent.
N,N'-Distearoylethylenediamine (*N,N'*ethylenebisstearamide).	
Epoxidized polybutadiene	For use only as a primer subcoat to anchor surface coatings to the base sheet.
Erucamide	
Ethyl acetate	
Ethylene-vinyl acetate copolymers complying with § 177.1350.	
2-Ethylhexyl alcohol	0.1 percent for use only as lubricant.
Fatty acids derived from animal and vegetable fats and oils, and the following salts of such acids, single or mixed: Aluminum, ammonium, calcium, magnesium, potassium, sodium.	
Ferrous ammonium sulfate	
Fumaric acid	
Glycerin-maleic anhydride	As the basic polymer.
Glycerol diacetate	
Glycerol monoacetate	
Hydroxyethyl cellulose, water-insoluble	
Hydroxypropyl cellulose identified in § 172.870 of this chapter.	
Isopropyl acetate	Residue limit 0.1 percent.
Isopropyl alcohol	Do.
Itaconic acid	
Lanolin	
Lauryl alcohol	
Lauryl sulfate salts: ammonium, magnesium, potassium, sodium.	
Maleic acid	1 percent.
Maleic acid adduct of butadienestyrene copolymer	
Melamine formaldehyde	As the basic polymer.
Melamine-formaldehyde modified with one or more of the following: Butyl alcohol, diaminopropane, diethylenetriamine, ethyl alcohol, guanidine, imino-bis-butylamine, imino-bis-ethylamine, imino-bis-propylamine, methyl alcohol, polyamines made by reacting ethylenediamine or trimethylenediamine with dichloroethane or dichloropropane, sulfanilic acid, tetraethylenepentamine, triethanolamine, triethylenetetramine.	As the basic polymer, and used as a resin to anchor coatings to substrate.
Methyl ethyl ketone	Residue limit 0.1 percent.
Methyl hydrogen siloxane	0.1 percent as the basic polymer.
α-Methylstyrene-vinyltoluene copolymer resins (molar ratio 1 α-methylstyrene to 3 vinyltoluene).	
Mineral oil, white	
Naphthalenesulfonic acid-formaldehyde condensate, sodium salt.	0.1 percent, for use only as an emulsifier.
Nitrocellulose, 10.9 percent–12.2 percent nitrogen	
Nylon resins complying with § 177.1500	
n-Octyl alcohol	For use only as a defoaming agent in the manufacture of cellophane base sheet.
Olefin copolymers complying with § 177.1520	
Oleic acid reacted with *N*-alkyl trimethylenediamine (alkyl C_{16} to C_{18}).	
Oleic acid, sulfonated, sodium salt	
Oleyl palmitamide	
N,N'-Oleoyl-stearylethylenediamine (*N*-(2-stearoylaminoethyl)oleamide).	
Paraffin, synthetic, complying with § 175.250 of this chapter.	
Pentaerythritol tetrastearate	0.1 percent.
Polyamide resins derived from dimerized vegetable oil acids (containing not more than 20 percent of monomer acids) and ethylenediamine as the basic resin.	For use only in cellophane coatings that contact food at temperatures not to exceed room temperature.
Polyamide resins having a maximum acid value of 5 and a maximum amine value of 8.5 derived from dimerized vegetable oil acids (containing not more than 10 percent monomer acids), ethylenediamine, and 4,4-bis(4-hydroxyphenyl)pentanoic acid (in an amount not to exceed 10 percent by weight of said polyamide resins).	As the basic resin, for use only in coatings that contact food at temperatures not to exceed room temperature provided that the concentration of the polyamide resins in the finished food-contact coating does not exceed 5 milligrams per square inch of food-contact surface.
Polybutadiene resin (molcular weight range 2,000–10,200; bromine number range 210–320).	For use only as an adjuvant in vinylidene chloride copolymer coatings.
Polycarbonate resins complying with § 177.1580	
Polyester resin formed by the reaction of the methyl ester of rosin, phthalic anhydride, maleic anhydride, and ethylene glycol, such that the polyester resin has an acid number of 4 to 11, a drop-softening point of 70° C–92° C, and a color of K or paler.	
Polyethylene	
Polyethyleneaminostearamide ethyl sulfate produced when stearic acid is made to react with equal parts of diethylenetriamine and triethylenetetramine and the reaction product is quaternized with diethyl sulfate.	0.1 percent.
Polyethylene glycol (400) monolaurate	
Polyethylene glycol (600) monolaurate	
Polyethylene glycol (400) monooleate	
Polyethylene glycol (600) monooleate	
Polyethylene glycol (400) monostearate	
Polyethylene glycol (600) monostearate	
Polyethylene, oxidized; complying with the identity prescribed in § 177.1620(a).	
Polyethylenimine	As the basic polymer, for use as a resin to anchor coatings to the substrate and for use as an impregnant in the food-contact surface of regenerated cellulose sheet in an amount not to exceed that required to improve heat-sealable bonding between coated and uncoated sides of cellophane.

	Limitations (residue and limits of addition expressed as percent by weight of finished packaging cellophane)
Polyisobutylene complying with § 177.1420	
Polyoxypropylene-polyoxyethylene block polymers (molecular weight 1,900–9,000).	For use as an adjuvant employed during the processing of cellulose pulp used in the manufacture of cellophane base sheet.
Polypropylene complying with § 177.1520	
Polystyrene	As the basic polymer.
Polyvinyl acetate	Do.
Polyvinyl alcohol (minimum viscosity of 4 percent aqueous solution at 20° C of 4 centipoises).	
Polyvinyl chloride	As the basic polymer.
Polyvinyl stearate	Do.
n-Propyl acetate	Residue limit 0.1 percent.
n-Propyl alcohol	Do.
Rapeseed oil, blown	
Rosins and rosin derivatives as provided in § 178.3870 of this chapter.	
Rubber, natural (natural latex solids)	
Silica	
Silicic acid	
Sodium *m*-bisulfite	
Sodium dioctyl sulfosuccinate	
Sodium dodecylbenzenesulfonate	
Sodium lauroyl sarcosinate	0.35 percent; for use only in vinylidene chloride copolymer coatings.
Sodium oleyl sulfate-sodium cetyl sulfate mixture	For use only as an emulsifier for coatings; limit 0.005 percent where coating is applied to one side only and 0.01 percent where coating is applied to both sides.
Sodium silicate	
Sodium stearoyl-2-lactylate identified in § 172.846 of this chapter.	Not to exceed 0.5 percent weight of cellophane.
Sodium sulfate	
Sodium sulfite	
Spermaceti wax	
Stannous oleate	
2-Stearamido-ethyl stearate	
Stearyl alcohol	
Styrene-maleic anhydride resins	As the basic polymer.
Terpene resins identified in § 172.615 of this chapter	
Tetrahydrofuran	Residue limit of 0.1 percent.
Titanium dioxide	
Toluene	Residue limit of 0.1 percent.
Toluene sulfonamide formaldehyde	0.6 percent as the basic polymer.
Triethylene glycol	
Triethylene glycol diacetate, prepared from triethylene glycol containing not more than 0.1 percent of diethylene glycol.	
2,2,4-Trimethyl-1,3 pentanediol diisobutyrate	For use only in cellophane coatings and limited to use at a level not to exceed 10 percent by weight of the coating solids except when used as provided in § 178.3740 of this chapter.
Urea (carbamide)	
Urea formaldehyde	As the basic polymer.
Urea formaldehyde modified with methanol, ethanol, butanol diethylenetriamine, triethylenetetramine, tetraethylenepentamine, guanidine, sodium sulfite, sulfanilic acid, imino-bis-ethylamine, imino-bis-propylamine, imino-bis-butylamine, diaminopropane, diaminobutane, aminomethylsulfonic acid, polyamines made by reacting ethylenediamine or trimethylenediamine with dichloroethane or dichloropropane.	As the basic polymer, and used as a resin to anchor coatings to the subtrate.
Vinyl acetate-vinyl chloride copolymer resins	As the basic polymer.
Vinyl acetate-vinyl chloride-maleic acid copolymer resins	Do.
Vinylidene chloride copolymerized with one or more of the following: Acrylic acid, acrylonitrile, butyl acrylate, butyl methacrylate, ethyl acrylate, 2-ethylhexyl acrylate, 2-ethylhexyl methacrylate, ethyl methacrylate, itaconic acid, methyacrylic acid, methyl acrylate, methyl methacrylate, propyl acrylate, propyl methacrylate, vinyl chloride.	Do.
Vinylidene chloride-methacrylate decyloctyl copolymer	Do.
Wax, petroleum, complying with § 178.3710 of this chapter	

(d) Any optional component listed in this section covered by a specific food additive regulation must meet any specifications in that regulation.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

§ 177.1210 Closures with sealing gaskets for food containers.

Closures with sealing gaskets may be safely used on containers intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) Closures for food containers are manufactured from substances generally recognized as safe for contact with food; substances that are subject to the provisions of prior sanctions; substances authorized by regulations in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter; and closure-sealing gaskets, as further prescribed in this section.

(b) Closure-sealing gaskets and overall discs are formulated from substances identified in §175.300(b) of this chapter, with the exception of paragraph (b)(3)(v), (xxxi), and (xxxii) of that section, and from other optional substances, including the following:

(1) Substances generally recognized as safe in food.

(2) Substances used in accordance with the provisions of a prior sanction or approval within the meaning of section 201(s) of the act.

(3) Substances that are the subject of regulations in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter and used in accordance with the conditions prescribed.

(4) Substances identified in paragraph (b)(5) of this section, used in amounts not to exceed those required to accomplish the intended physical or

technical effect and in conformance with any limitation provided; and further provided that any substance employed in the production of closure-sealing gasket compositions that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with the identity or specifications prescribed.

(5) Substances that may be employed in the manufacture of closure-sealing gaskets include:

Table 1

List of substances	*Limitations (expressed as percent by weight of closure-sealing gasket composition)*
Arachidyl-behenyl amide (C_{20}-C_{22} fatty acid amides)	5 percent.
Azodicarbonamide	2 percent.
Balata rubber	
Benzyl alcohol	1 percent.
1,3-Butanediol	
Calcium tin stearate	2 percent.
Calcium zinc stearate	2 percent.
Carbon, activated	1 percent.
Castor oil, hydrogenated	2 percent.
Chlorinated isobutylene-isoprene copolymers complying with § 177.1420.	
Coco amide (coconut oil fatty acids amides)	2 percent.
Cork (cleaned, granulated)	
Dibenzamide phenyl disulfide	1 percent; for use only in vulcanized natural or synthetic rubber gasket compositions.
Di(C_7,C_9-alkyl) adipate	Complying with § 178.3740 of this chapter; except that, there is no limitation on polymer thickness.
Di-2-ethylhexyl adipate	
Di-2-ethylhexyl sebacate	2 percent.
Dihexyl ester of sodium sulfosuccinate	1 percent.
Diisodecyl phthalate	No limitation on amount used but for use only in closure-sealing gasket compositions used in contact with non-fatty foods containing no more than 8 percent of alcohol.
Di-β-naphthyl-*p*-phenylenediamine	1 percent.
Dipentamethylenethiuramtetrasulfide	0.4 percent; for use only in vulcanized natural or synthetic rubber gasket compositions.
Eicosane (technical grade) (water-white mixture of predominantly straight-chain paraffin hydrocarbons averaging 20 carbon atoms per molecule).	
Epoxidized linseed oil	
Epoxidized linseed oil modified with trimellitic anhydride.	
Epoxidized safflower oil	
Epoxidized safflower oil modified with trimellitic anhydride.	
Epoxidized soybean oil modified with trimellitic anhydride.	
Erucylamide	5 percent.
Ethylene-propylene copolymer	
Ethylene-propylene modified copolymer elastomers produced when ethylene and propylene are copolymerized with 5-methylene-2-norbornene and/or 5-ethylidine-2-norbornene. The finished copolymer elastomers so produced shall contain not more than 5 weight-percent of total polymer units derived from 5-methylene-2-norbornene and/or 5-ethylidine-2-norbornene, and shall have a minimum viscosity average molecular weight of 120,000 as determined by the method described in § 177.1520(d)(5), and a minimum Mooney viscosity of 35 as determined by the method described in § 177.1520(d)(6).	
Ethylene-vinyl acetate copolymer	
Glyceryl mono-12-hydroxystearate (hydrogenated glyceryl ricinoleate).	2 percent.
Gutta-percha	
Hexamethylenetetramine	1 percent.
Hexylene glycol	0.5 percent.
Isobutylene-isoprene copolymers complying with § 177.1420.	
Maleic anhydride-polyethylene copolymer	5 percent.
Maleic anhydride-styrene copolymer	5 percent.
2,2'-Methylenebis[6-(1-methylcyclohexyl)-*p*-cresol]	1 percent.
Naphthalene sulfonic acid-formaldehyde condesnate, sodium salt.	0.2 percent.
Natural rubber (crepe, latex, mechanical dispersions)	0.5 percent.
α-cis-9-Octadecenyl-*omega*-hydroxypoly (oxyethylene); the octadecenyl group is derived from oleyl alcohol and the poly (oxyethylene) content averages 20 moles.	
Oleyl alcohol	1 percent.
4,4'-Oxybis (benzene sulfonyl hydrazide)	0.5 percent.
Paraformaldehyde	1 percent.
Polybutadiene	
Poly-*p*-dinitroso benzene (activator for butyl rubber)	1 percent; for use only in vulcanized natural or synthetic rubber gasket compositions.
Polyethylene glycol 400 esters of fatty acids derived from animal and vegetable fats and oils.	1 percent.
Polyisobutylene complying with § 177.1420	
Polyoxypropylene-polyoxyethylene condensate, average mol. wt. 2750–3000.	0.05 percent.
Potassium benzoate	1 percent.
Potassium perchlorate	1 percent.
Potassium propionate	2 percent.
Potassium and sodium persulfate	1 percent.
Resorcinol	0.24 percent; for use only as a reactive adjuvant substance employed in the production of gelatin-bonded cord compositions for use in lining crown closures. The gelatin so used shall be technical grade or better.
Rosins and rosin derivatives as defined in § 175.300(b)(3)(v) of this chapter for use only in resinous and polymeric coatings on metal substrates; for all other uses as defined in § 178.3870 of this chapter.	
Sodium cetyl sulfate	1 percent.
Sodium decylbenzenesulfonate	1 percent.
Sodium decyl sulfate	1 percent.
Sodium formaldehyde sulfoxylate	0.05 percent.

Sodium lauryl sulfate	1 percent.
Sodium lignin sulfonate	0.2 percent.
Sodium myristyl sulfate (sodium tetradecyl sulfate)	0.6 percent.
Sodium nitrite	0.2 percent; for use only in annular ring gaskets applied in aqueous dispersions to closures for containers having a capacity of not less than 5 gallons.
Sodium o-phenylphenate	0.05 percent.
Sodium polyacrylate	5 percent.
Sodium and potassium pentachlorophenate	0.05 percent.
Sodium salt of trisopropyl naphthalenesulfonic acid	0.2 percent.
Sodium tridecylsulfate	0.6 percent.
Stearic acid amide	5 percent.
Sulfur	For use only as a vulcanizing agent in vulcanized natural or synthetic rubber gasket compositions at a level not to exceed 4 percent by weight of the elastomer content of the rubber gasket composition.
Tallow, sulfated	1 percent.
Tin-zinc stearate	2 percent.
Tri(mixed mono- and dinonylphenyl) phosphite	1 percent.
Vinyl chloride-vinyl copolymer	
Zinc dibutyldithiocarbamate	0.8 percent; for use only in vulcanized natural or synthetic rubber gasket compositions.

TABLE 2.—*Maximum extractives tolerances*

[In parts per million]

Type of closure-sealing gasket composition	Chloroform fraction of water extractives	Chloroform fraction of heptane extractives	Chloroform fraction of alcohol extractives
1. Plasticized polymers, including unvulcanized or vulcanized or otherwise cured natural and synthetic rubber formed in place as overall discs or annular rings from a hot melt, solution, plastisol, organisol, mechanical dispersion, or latex	50	500	50
2. Preformed overall discs or annular rings of plasticized polymers, including unvulcanized natural or synthetic rubber	50	250	50
3. Preformed overall discs or annular rings of vulcanized plasticized polymers, including natural or synthetic rubber	50	50	50
4. Preformed overall discs or annular rings of polymeric or resinous-coated paper, paperboard, plastic, or metal foil substrates	50	250	50
5. Closures with sealing gaskets or sealing compositions as described in 1, 2, 3, and 4, and including paper, paperboard, and glassine used for dry foods only	(1)	(1)	(1)

[1] Extractability tests not applicable.

(c) The closure assembly to include the sealing gasket or sealing compound, together with any polymeric or resinous coating, film, foil, natural cork, or glass that forms a part of the food-contact surface of the assembly, when extracted on a suitable glass container with a solvent or solvents characterizing the type of foods, and under conditions of time and temperature characterizing the conditions of its use as determined from Tables 3 and 4 shall yield net chloroform-soluble extractives (corrected for zinc as zinc oleate) not to exceed the tolerances specified in Table 2, calculated on the basis of the water capacity of the container on which the closure is to be used. Employ the analytical method described in § 175.300 of this chapter, adapting the procedural details to make the method applicable to closures; such as, for example, placing the closed glass container on its side to assure contact of the closure's food-contacting surface with the solvent.

TABLE 3—TYPES OF FOOD

I. Nonacid (pH above 5.0), aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
II. Acidic (pH 5.0 or below), aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
IV. Dairy products and modifications:
  A. Water-in-oil emulsions, high- or low-fat.
  B. Oil-in-water emulsions, high- or low-fat.
V. Low-moisture fats and oils.
VI. Beverages:
  A. Containing alcohol.
  B. Nonalcoholic.
VII. Bakery products.
VIII. Dry solids (no end-test required).

TABLE 4.— *Test procedures with time-temperature conditions for determining amount of extractives from closure-sealing gaskets, using solvents simulating types of foods and beverages*

Conditions of use	Types of food (see Table 3)	Extractant		
		Water (time and temperature)	Heptane [1] (time and temperature)	8 pct alcohol (time and temperature)
A. High temperature heat-sterilized (e.g., over 212° F).	I, IV-B	250° F, 2 hr.		
	III, IV-A, VII	Do.	150° F, 2 hr.	
B. Boiling water-sterilized	II	212° F, 30 min.		
	III, VII		120° F, 30 min.	
C. Hot filled or pasteurized above 150° F.	II, IV-B	Fill boiling, cool to 100° F.		
	III, IV-A		120° F, 15 min.	
	V		Do.	
D. Hot filled or pasteurized below 150° F.	II, IV-B, VI-B	150° F, 2hr.		
	III, IV-A		100° F, 30 min.	
	V		Do.	
	VI-A			150° F, 2 hr.
E. Room temperature filled and stored (no thermal treatment in the container).	II, IV-B, VI-B	120° F, 24 hr.		
	III, IV-A		70° F, 30 min.	
	V		Do.	
	VI-A			120° F, 24 hr.
F. Refrigerated storage (no thermal treatment in the container).	I, II III, IV-A, IV-B, VI-B, VII	70° F, 48 hr.	70° F, 30 min.	
	VI-A			70° F, 48 hr.
G. Frozen storage (no thermal treatment in the container).	I, II, III, IV-B VII	70° F, 24 hr.		

[1] Heptane extractant not applicable to closure-sealing gaskets overcoated with wax.

§ 177.1240 1,4-Cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate copolymer.

Copolymer of 1,4-cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate may be safely used as an article or component of articles used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

(a) The copolymer is a basic polyester produced by the catalytic condensation of dimethyl terephthalate and dimethyl isophthalate with cyclohexanedimethanol-1.4, to which may have been added certain optional substances required in its production or added to impart desired physical and technical properties.

(b) The quantity of any optional substance employed in the production of the copolymer does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation further provided.

(c) Any substance employed in the production of the copolymer that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

(d) Substances employed in the production of the copolymer include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in the copolymer and used in accordance with such sanction or approval.

(3) Substances which by regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter may be safely used as components of resinous or polymeric coatings and film used as food-contact surfaces, subject to the provisions of such regulation.

(e) The copolymer conforms with the following specifications:

(1) The copolymer, when extracted with distilled water at reflux temperature for 2 hours, yields total extractives not to exceed 0.05 percent.

(2) The copolymer, when extracted with ethyl acetate at reflux temperature for 2 hours, yields total extractives not to exceed 0.7 percent.

(3) The copolymer, when extracted with *n*-hexane at reflux temperature for 2 hours, yields total extractives not to exceed 0.05 percent.

§ 177.1310 Ethylene-acrylic acid copolymers.

The ethylene-acrylic acid copolymers identified in pararaph (a) of this section may be safely used as components of articles intended for use in contact with food subject to the provisions of this section.

(a) For the purpose of this section, ethylene-acrylic acid copolymers consist of basic copolymers produced by the copolymerization of ethlene and acrylic acid such that the finished basic copolymers contain no more than 10 weight-percent of total polymer units derived from acrylic acid.

(b) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of its intended use as determined from Tables 1 and 2 of § 176.170(c) of this chapter, yields net acidified chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface when tested by the methods prescribed in § 177.1330 (c), except that net acidified chloroform-soluble extractives from paper and paperboard complying with § 176.170 of this chapter may be corrected for wax, petrolatum, and mineral oil as provided in § 176.170(d)(5)(iii)(*b*) of this chapter. If the finished food-contact article is itself the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation. (NOTE: In testing the finished food-contact article, use a separate test sample for each extracting solvent.)

(c) The provisions of this section are not applicable to ethylene-acrylic acid copolymers used in food-packaging adhesives complying with § 175.105 of this chapter.

§ 177.1320 Ethylene-ethyl acrylate copolymers.

Ethylene-ethyl acrylate copolymers may be safely used to produce packaging materials, containers, and equipment intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) Ethylene-ethyl acrylate copolymers consist of basic resins produced by the catalytic copolymerization of ethylene and ethyl acrylate, to which may have been added certain optional substances to impart desired technological properties to the resin. Subject to any limitations prescribed in this section, the optional substances may include:

(1) Substances generally recognized as safe in food and food packaging.

(2) Substances the use of which is permitted under applicable regulations in Parts 170 through 189 of this chapter, prior sanction, or approvals.

(b) The ethyl acrylate content of the copolymer does not exceed 8 percent by weight unless it is blended with polyethylene or with one or more olefin copolymers complying with § 177.1520 or with a mixture of polyethylene and one or more olefin copolymers, in such proportions that the ethyl acrylate content of the blend does not exceed 8 percent by weight, or unless it is used in a coating complying with § 175.300 or § 176.170 of this chapter, in such proportions that the ethyl acrylate content does not exceed 8 percent by weight of the finished coating.

(c) Ethylene-ethyl acrylate copolymers or the blend shall conform to the specifications prescribed in paragraph (c)(1) of this section and shall meet the ethyl acrylate content limits prescribed in paragraph (b) of this section, and the extractability limits prescribed in paragraph (c)(2) of this section, when tested by the methods prescribed for polyethylene in § 177.1520.

(1) *Specifications*—(i) *Infrared identification.* Ethylene-ethyl acrylate copolymers can be identified by their characteristic infrared spectra.

(ii) *Quantitative determination of ethyl acrylate content.* The ethyl acrylate can be determined by the infrared spectra. Prepare a scan from 10.5 microns to 12.5 microns. Obtain a baseline absorbance at 11.6 microns and divide by the plaque thickness to obtain absorbance per mil. From a previously prepared calibration curve, obtain the amount of ethyl acrylate present.

(iii) *Specific gravity.* Ethylene-ethyl acrylate copolymers have a specific gravity of not less than 0.920 nor more than 0.935, as determined by A.S.T.M. Method D–1505.

(2) *Limitations.* Ethylene-ethyl acrylate copolymers or the blend may be used in contact with food except as a component of articles used for packaging or holding food during cooking provided they meet the following extractability limits:

(i) Maximum soluble fraction of 11.3 percent in xylene after refluxing and subsequent cooling to 25° C.

(ii) Maximum extractable fraction of 5.5 percent when extracted with *n*-hexane at 50° C.

(d) The provisions of paragraphs (b) and (c) (2) of this section are not applicable to ethylene-ethyl acrylate copolymers used in the formulation of adhesives complying with § 175.105 of this chapter.

§ 177.1330 Ethylene-methacrylic acid copolymers, ethylene-methacrylic acid-vinyl acetate copolymers, and their partial salts.

Ethylene-methacrylic acid copolymers, ethylene-methacrylic acid-vinyl acetate copolymers, and/or their ammonium, calcium magnesium, sodium, and/or zinc partial salts may be safely used as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, the ethylene-methacrylic acid copolymers consist of basic copolymers produced by the copolymerization of ethylene and methacrylic acid such that the copolymers contain no more than 20 weight percent of polymer units derived from methacrylic acid, and the ethylene-methacrylic acid-vinyl acetate copolymers consist of basic copolymers produced by the copolymerization of ethylene, methacrylic acid, and vinyl acetate such that the copolymers contain no more than 15 weight percent of polymer units derived from methacrylic acid.

(b) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of § 176.170(c) of this chapter, yields net acidified chloroform-soluble extractives in each extracting solvent not to exceed 0.5 milligram per square inch of food-contact surface when tested by the methods described in paragraph (c) of this section; and if the finished food-contact article is itself the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation. (NOTE: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.)

(c) *Analytical methods*—(1) *Selection of extractability conditions.* First ascertain the type of food (table 1 of § 176.170(c) of this chapter) that is being packed or used in contact with the finished food-contact article described in paragraph (b) of this section, and also ascertain the normal conditions of thermal treatment used in packaging or contacting the type of food involved. Using table 2 of § 176.170(c) of this chapter, select the food-simulating solvent or solvents and the time-temperature test conditions that correspond to the intended use of the finished food-contact article. Having selected the appropriate food-simulating solvent or solvents and time-temperature exaggeration over normal use, follow the applicable extraction procedure.

(2) *Reagents*—(i) *Water.* All water used in extraction procedures should be freshly demineralized (deionized), distilled water.

(ii) *n-Heptane.* Reagent grade, freshly redistilled before use, using only material boiling at 208° F.

(iii) *Alcohol.* 8 or 50 percent (by volume), prepared from undenatured 95 percent ethyl alcohol diluted with demineralized (deionized), distilled water.

(iv) *Chloroform.* Reagent grade, freshly redistilled before use, or a grade having an established, consistently low blank.

(3) *Selection of test method.* The finished food-contact articles shall be tested either by the extraction cell described in the Journal of the Association of Official Agricultural Chemists, Volume 47, No. 1, pages 177–179 (February 1964), also described in ASTM Method F 34–63T, or by adapting the in-container methods described in § 175.300(e) of this chapter.

(4) *Selection of samples.* Quadruplicate samples should be tested, using for each replicate sample the number of finished articles with a food-contact surface nearest to 100 square inches.

(5) *Determination of amount of extractives*—(i) *Total residues.* At the end of the exposure period, remove the test container or test cell from the oven, if any, and combine the solvent for each replicate in a clean Pyrex (or equivalent) flask or beaker, being sure to rinse the test container or cell with a small quantity of clean solvent. Evaporate the food-simulating solvents to about 100 milliliters in the flask, and transfer to a clean, tared evaporating dish (platinum or Pyrex), washing the flask three times with small portions of solvent used in the extraction procedure, and evaporate to a few milliliters on a nonsparking, low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at a temperature of 221° F. Cool the evaporating dish in a desiccator for 30 minutes and weigh the residues to the nearest 0.1 milligram, *e*. Calculate the extractives in milligrams per square inch of the container or material surface.

(a) *Water and 8- and 50-percent alcohol.* Milligrams extractives per square inch $= \frac{e}{a}$.

(b) *Heptane.* Milligrams extractives per square inch $= \frac{e}{(a)\,(F)}$

where:

e = Milligrams extractives per sample tested.
a = Surface area tested, in square inches.
F = Five, the ratio of the amount of extractives removed by heptane under exaggerated time-temperature test conditions compared to the amount extracted by a fat or oil under exaggerated conditions of thermal sterilization and use.
Acidified chloroform-soluble extractives residue.
e' is substituted for e in the above equations when necessary.

If when calculated by the equations in paragraph (c) (5) (i) (*a*) and (*b*) of this section, the extractives in milligrams per square inch exceed the limitations prescribed in paragraph (b) of this section, proceed to paragraph (c) (5) (ii) of this section (method for determining the amount of acidified chloroform-soluble extractives residue).

(ii) *Acidified chloroform-soluble extractives residue.* Add 3 milliliters of 37 percent ACS reagent grade hydrochloric acid and 3 milliliters of distilled water to the evaporating dish containing the dried and weighed residue, *e*, obtained in paragraph (c) (5) (i) of this section. Mix well so every portion of the residue is wetted with the hydrochloric acid solution. Then add 50 milliliters of chloroform. Warm carefully, and filter through Whatman No. 41 filter paper (or equivalent) in a Pyrex (or equivalent) funnel, collecting the filtrate in a clean separatory funnel, shake for 1 minute, then draw off the chloroform layer into a clean tared evaporating dish (platinum or Pyrex). Repeat the chloroform extraction, washing the dish, the filter paper, and the separatory funnel with this second portion of chloroform. Add this filtrate to the original filtrate and evaporate the total down to a few milliliters on a low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at 221° F. Cool the evaporating dish in a desiccator for 30 minutes and weigh to the nearest 0.1 milligram to get the acidified chloroform-soluble extractives residue, *e'*. This *e'* is substituted for *e* in the equations in paragraph (c) (5) (i) (*a*) and (*b*) of this section.

(d) The provisions of paragraph (b) of this section are not applicable to the ethylene-methracrylic acid copolymers, ethylene-methacrylic acid-vinyl acetate copolymers, and/or their ammonium, calcium, magnesium, sodium, and/or zinc partial salts used in food-packing adhesives complying with § 175.105 of this chapter.

§ 177.1340 Ethylene-methyl acrylate copolymer resins.

Ethylene-methyl acrylate copolymer resins may be safely used as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section,

the ethylene-methyl acrylate copolymer resins consist of basic copolymers produced by the copolymerization of ethylene and methyl acrylate such that the copolymers contain no more than 25 weight percent of polymer units derived from methyl acrylate.

(b) The finshed food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of § 176.170(c) of this chapter, yields net chloroform-soluble extractives (corrected for zinc extractives as zinc oleate) in each extracting solvent not to exceed 0.5 milligram per square inch of food-contact surface when tested by the methods described in § 176.170(d) of this chapter. If the finished food-contact article is itself the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation.

NOTE.—In testing the finshed food-contact article, use a separate test sample for each required extracting solvent.

(c) The provisions of this section are not applicable to ethylene-methyl acrylate copolymer resins used in food-packaging adhesives complying with § 175.105 of this chapter.

§ 177.1350 Ethylene-vinyl acetate copolymers.

Ethylene-vinyl acetate copolymers may be safely used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) Ethylene-vinyl acetate copolymers consist of basic resins produced by the catalytic copolymerization of ethylene and vinyl acetate to which may have been added certain optional substances to impart desired technological or physical properties to the resin. Subject to any limitations prescribed in this section, the optional substances may include:

(1) Substances generally recognized as safe in food and food packaging.

(2) Substances the use of which is permitted under applicable regulations in Parts 170 through 189 of this chapter, prior sanction, or approvals.

(3) Substances identified in § 175.300 (b)(3) (xxv), (xxvi), (xxvii), (xxx), and (xxxiii) of this chapter.

(4) Erucamide as identified in § 178.3860 of this chapter.

(b) Ethylene-vinyl acetate copolymers, with or without the optional substances described in paragraph (a) of this section, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of their intended use as determined from Tables 1 and 2 of § 176.170(c) of this chapter, shall yield net chloroform-soluble extractives corrected for zinc as zinc oleate not to exceed 0.5 milligram per square inch of an appropriate sample.

(c) The provisions of paragraph (b) of this section are not applicable to ethylene-vinyl acetate copolymers used in food-packaging adhesives complying with § 175.105 of this chapter.

(d) Ethylene-vinyl acetate copolymers may be irradiated under the following conditions to produce molecular crosslinking of the polymers to impart desired properties such as increased strength and increased ability to shrink when exposed to heat:

(1) Electron beam source of ionizing radiation at a maximum energy of 3 million electron volts; maximum absorbed dose not to exceed 8 megarads.

(2) The finished food-contact film shall meet the extractives limitations prescribed in paragraph (e)(2) of this section.

(3) The ethylene-vinyl acetate copolymer films may be further irradiated in accordance with the provisions of paragraph (e)(1) of this section: *Provided*, That the total accumulated radiation dose from both electron beam and gamma ray radiation does not exceed 8.0 megarads.

(e) Ethylene-vinyl acetate copolymer films intended for contact with food may be irradiated to control the growth of microorganisms under the following conditions:

(1) Gamma photons emitted from a cobalt-60 sealed source in the dose range of 0.5–5.0 megarads.

(2) The irradiated ethylene-vinyl acetate copolymer films, when extracted with reagent grade n-heptane (freshly redistilled before use) according to methods described under § 176.170(d)(3) of this chapter, at 75° F for 30 minutes shall yield total extractives not to exceed 4.5 percent by weight of the film.

§ 177.1360 Ethylene-vinyl acetate-vinyl alcohol copolymers.

Ethylene-vinyl acetate-vinyl alcohol copolymers may be safely used as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) Ethylene-vinyl acetate-vinyl alcohol copolymers are produced by the partial or complete alcoholysis or hydrolysis of those ethylene-vinyl acetate copolymers complying with § 177.1350 and containing a minimum of 55 percent ethylene such that the finished ethylene-vinyl acetate-vinyl alcohol copolymers will contain no more than 30 percent vinyl alcohol units by weight.

(b) The finished food contact article shall not exceed 0.005 inch thickness and shall contact foods only of the types identified in table 1 of § 176.170(c) of this chapter in categories I, II, IV–B, VI, VII–B, and VIII under the conditions of use D through G described in table 2 of § 176.170(c) of this chapter: *Provided*, That film samples of 0.005 inch thickness representing the finished article meet the following extractives limitation when tested by ASTM Method F34–63T:

(1) The film when extracted with distilled water at 70° F for 48 hours yields total extractives not to exceed 0.03 milligrams per square inch of food-contact surface.

(2) The film when extracted with 50 percent alcohol at 70° F for 48 hours yields total extractives not to exceed 0.04 milligram per square inch of food-contact surface.

(c) The provisions of this section are not applicable to ethylene-vinyl acetate-vinyl alcohol copolymers used in the food packaging adhesives complying with § 175.105 of this chapter.

§ 177.1380 Fluorocarbon resins.

Fluorocarbon resins may be safely used as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, fluorocarbon resins consist of basic resins produced as follows:

(1) Chlorotrifluoroethylene resins produced by the homopolymerization of chlorotrifluoroethylene.

(2) Chlorotrifluoroethylene-1,1-difluoroethylene copolymer resins produced by copolymerization of chlorotrifluoroethylene and 1,1-difluoroethylene.

(3) Chlorotrifluoroethylene-1,1-difluoroethylene-tetrafluoroethylene copolymer resins produced by copolymerization of chlorotrifluoroethylene, 1,1-difluoroethylene, and tetrafluoroethylene.

(b) Fluorocarbon resins that are identified in paragraph (a) of this section and that comply with the extractives limitations prescribed in paragraph (c) of this section may be used as articles or components of articles intended for use in contact with food. Fluorocarbon resins that are identified in paragraph (a) of this section and that comply only with the extractives limitations prescribed in paragraph (c) (1) and (2) of this section may be used when such use is limited to articles or components of articles that are intended for repeated use in contact with food or that are intended for one-time use in contact with food only of the types identified in § 176.170(c) of this chapter, table 1, under types I, II, VI, VII–B, and VIII. In accordance with good manufacturing practice, those food-contact articles intended for repeated use shall be thoroughly cleansed prior to their first use in contact with food.

(c) Extractives limitations are applicable to the basic resins in the form of pellets that have been ground or cut into small particles that will pass through a U.S. Standard Sieve No. 6 and that will be held on a U.S. Standard Sieve No. 10.

(1) A 100-gram sample of the resin pellets, when extracted with 100 milliliters of distilled water at reflux temperature for 8 hours, shall yield total extractives not to exceed 0.003 percent by weight of the resins.

(2) A 100-gram sample of the resin pellets, when extracted with 100 milli-

liters of 50 percent (by volume) ethyl alcohol in distilled water at reflux temperature for 8 hours, shall yield total extractives not to exceed 0.003 percent by weight of the resins.

(3) A 100-gram sample of the resin pellets, when extracted with 100 milliliters of *n*-heptane at reflux temperature for 8 hours, shall yield total extractives not to exceed 0.01 percent by weight of the resins.

§ 177.1400 Hydroxyethyl cellulose film, water-insoluble.

Water-insoluble hydroxyethyl cellulose film may be safely used for packaging food in accordance with the following prescribed conditions:

(a) Water-insoluble hydroxyethyl cellulose film consists of a base sheet manufactured by the ethoxylation of cellulose under controlled conditions, to which may be added certain optional substances of a grade of purity suitable for use in food packaging as constituents of the base sheet or as coatings applied to impart desired technological properties.

(b) Subject to any limitations prescribed in Parts 170 through 189 of this chapter, the optional substances used in the base sheet and coating may include:

(1) Substances generally recognized as safe in food.

(2) Substances permitted to be used in water-insoluble hydroxyethyl cellulose film by prior sanction or approval and under conditions specified in such sanctions or approval, and substances listed in § 181.22 of this chapter.

(3) Substances that by any regulation promulgated under section 409 of the act may be safely used as components of water-insoluble hydroxyethyl cellulose film.

(4) Substances identified in and used in compliance with § 177.1200(c).

(c) Any substance employed in the production of the water-insoluble hydroxyethyl cellulose film described in this section that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

§ 177.1420 Isobutylene polymers.

Isobutylene polymers may be safely used as components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, isobutylene polymers are those produced as follows:

(1) Polyisobutylene produced by the homopolymerization of isobutylene such that the finished polymers have a molecular weight of 750,000 (Flory) or higher.

(2) Isobutylene-isoprene copolymers produced by the copolymerization of isobutylene with not more than 3 molar percent of isoprene such that the finished polymers have a molecular weight of 300,000 (Flory) or higher.

(3) Chlorinated isobutylene-isoprene copolymers produced when isobutylene-isoprene copolymers (molecular weight 300,000 (Flory) or higher) are modified by chlorination with not more than 1.3 weight-percent of chlorine.

(b) The polymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of the polymers. The optional adjuvant substances required in the production of the polymers may include substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, and aluminum chloride.

(c) The provisions of this section are not applicable to polyisobutylene used in food-packaging adhesives complying with § 175.105 of this chapter.

§ 177.1430 Isobutylene-butene copolymers.

Isobutylene-butene copolymers identified in this section may be safely used as components of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) For the purpose of this section, isobutylene-butene copolymers consist of basic copolymers produced by the copolymerization of isobutylene with mixtures of *n*-butenes such that the finished basic copolymers contain not less than 45 weight percent of polymer units derived from isobutylene and meet the following specifications:

(1) Average molecular weight is in the range 300–5,000 as determined by ASTM Method D 2503.

(2) Viscosity is in the range 40–20,000 seconds Saybolt at 200° F as determined by ASTM Method D 445.

(3) Maximum bromine value is 40 as determined by ASTM Method D 1492.

(b) The isobutylene-butene basic copolymers are limited to use:

(1) As a release agent in petroleum wax complying with § 178.3710 of this chapter.

(2) As a plasticizer in polyethylene complying with § 177.1520 and in polystyrene complying with § 177.1640.

(3) As a component of nonfood articles complying with §§ 175.300, 176.-170, 176.210, 177.2260(d)(2), 177.2800, 178.3570 (provided that addition to food does not exceed 10 parts per million), or § 176.180 of this chapter.

(c) The provisions of this section are not applicable to isobutylene-butene copolymers used as provided under § 175.105 of this chapter.

§ 177.1440 4,4'-Isopropylidenediphenol-epichlorohydrin resins minimum molecular weight 10,000.

4,4'-Isopropylidenediphenol-epichlorohydrin resins having a minimum molecular weight of 10,000 may be safely used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) 4,4' - Isopropylidenediphenol-epichlorohydrin resins consist of basic resins produced by the condensation of equimolar amounts of 4,4'-isopropylidenediphenol and epichlorohydrin terminated with phenol, to which may have been added certain optional adjuvant substances required in the production of the resins.

(b) The optional adjuvant substances required in the production of the resins may include substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, and the following:

List of substances	*Limitations*
Butyl alcohol	Not to exceed 300 p.p.m. as residual solvent in finished resin.
Ethyl alcohol	----------
Toluene	Not to exceed 1,000 p.p.m. as residual solvent in finished resin.

(c) 4,4'-Isopropylidenediphenol - epichlorohydrin resins shall meet the following nonvolatile extractives limitations:

(1) Maximum extractable nonvolatile fraction of 2 parts per million when extracted with distilled water at 70° C for 2 hours, using a volume-to-surface ratio of 2 milliliters per square inch.

(2) Maximum extractable nonvolatile fraction of 3 parts per million when extracted with *n*-heptane at 70° C for 2 hours, using a volume-to-surface ratio of 2 milliliters per square inch.

(3) Maximum extractable nonvolatile fraction of 6 parts per million when extracted with 10 percent (by volume) ethyl alcohol in distilled water at 70° C for 2 hours, using a volume-to-surface ratio of 2 milliliters per square inch.

(d) The provisions of this section are not applicable to 4,4'-isopropylidenediphenol-epichlorohydrin resins listed in other sections of Subchapter B of this chapter.

§ 177.1460 Melamine-formaldehyde resins in molded articles.

Melamine-formaldehyde resins may be safely used as the food-contact surface of molded articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) For the purpose of this section, melamine-formaldehyde resins are those produced when 1 mole of melamine is made to react with not more than 3 moles of formaldehyde in water solution.

(b) The resins may be mixed with refined woodpulp and the mixture may contain other optional adjuvant substances which may include the following:

List of substances	*Limitations*
Dioctyl phthalate	For use as lubricant.
Hexamethylenetetra - mine.	For use only as polymerization reaction control agent
Phthalic acid anhydride.	Do.
Pigments and colorants identified in § 175.300(b)(3)(xxvi) of this chapter.	----------
Zinc stearate	For use as lubricant.

(c) The molded melamine-formaldehyde articles in the finished form in which they are to contact food, when extracted with the solvent or solvents

characterizing the type of food and under the conditions of time and temperature as determined from tables 1 and 2 of § 175.300(d) of this chapter, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface.

§ 177.1480 Nitrile rubber modified acrylonitrile-methyl acrylate copolymers.

Nitrile rubber modified acrylonitrile-methyl acrylate copolymers identified in this section may be safely used as components of articles intended for food-contact use under conditions of use D, E, F, or G described in table 2 of § 176.170 (c) of this chapter, subject to the provisions of this section.

(a) For the purpose of this section, nitrile rubber modified acrylonitrile-methyl acrylate copolymers consist of basic copolymers produced by the graft copolymerization of 73–77 parts by weight of acrylonitrile and 23–27 parts by weight of methyl acrylate in the presence of 8–10 parts by weight of butadiene-acrylonitrile copolymers containing approximately 70 percent by weight of polymer units derived from butadiene.

(b) The nitrile rubber modified acrylonitrile-methyl acrylate basic copolymers meet the following specifications and extractives limitations:

(1) *Specifications.* (i) Nitrogen content is in the range 16.5–19 percent as determined by Kjeldahl analysis.

(ii) Intrinsic viscosity in acetonitrile at 25° C is not less than 0.29 deciliter per gram as determined by ASTM Method D 1243–60.

(iii) Residual acrylonitrile monomer content is not more than 11 parts per million as determined by gas chromatography.

(iv) Acetonitrile-soluble fraction after refluxing the base polymer in acetonitrile for 1 hour is not greater than 95 percent by weight of the basic copoylmers.

(2) *Extractives limitations.* The following extractives limitations are determined by an infrared spectrophotometric method, available upon request from the Commissioner of Food and Drugs, and are applicable to the basic copolymers in the form of particles of a size that will pass through a U.S. sandard sieve No. 6 and that will be held on a U.S. standard sieve No. 10:

(i) Extracted copolymer not to exceed 2.0 parts per million in aqueous extract obtained when a 100-gram sample of the basic copolymers is extracted with 250 milliliters of demineralized (deionized) water at reflux temperature for 2 hours.

(ii) Extracted copolymer not to exceed 0.5 part per million in *n*-heptane extract obtained when a 100-gram sample of the basic copolymers is extracted with 250 milliliters of reagent grade *n*-heptane at reflux temperature for 2 hours.

(c) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

NOTE: § 177.1480 (formerly § 121.2614, insofar as it permits a nitrile rubber modified acrylonitrile-methyl acrylate copolymer to be used to fabricate beverage containers, was stayed by an order published in the FEDERAL REGISTER of March 11, 1977 (42 FR 13546).

§ 177.1500 Nylon resins.

The nylon resins listed in paragraph (a) of this section may be safely used to produce articles intended for use in processing, handling, and packaging food, subject to the provisions of this section:

(a) The nylon resins are manufactured as described in this paragraph so as to meet the specifications prescribed in paragraph (b) of this section when tested by the methods described in paragraph (c) of this section.

(1) Nylon 66 resins are manufactured by the condensation of hexamethylenediamine and adipic acid.

(2) Nylon 610 resins are manufactured by the condensation of hexamethylenediamine and sebacic acid.

(3) Nylon 66/610 resins are manufactured by the condensation of equal-weight mixtures of nylon 66 salts and nylon 610 salts.

(4) Nylon 6/66 resins are manufactured by the condensation and polymerization of mixtures of nylon 66 salts and *epsilon*-caprolactam under such conditions that the *epsilon*-caprolactam monomer content does not exceed 0.7 percent by weight of the finished nylon 6/66 resins.

(5) Nylon 11 resins are manufactured by the condensation of 11-aminoundecanoic acid.

(6) Nylon 6 resins are manufactured by the polymerization of *epsilon*-caprolactam.

(7) Nylon 66T resins are manufactured by the condensation of hexamethylenediamine, adipic acid, and terephthalic acid such that composition in terms of ingredients is 43.1 ± 0.2 weight percent hexamethylenediamine, 35.3 ± 1.2 weight percent adipic acid, and 21.6 ± 1.2 weight percent terephthalic acid.

(8) Nylon 612 resins are manufactured by the condensation of hexamethylenediamine and dodecanedioic acid.

(9) Nylon 12 resins are manufactured by the condensation of *omega*-laurolactam.

(b) Specifications:

Nylon resins	Specific gravity	Melting point (degrees Fahrenheit)	Solubility in boiling 4.2*N* HCl	Maximum extractable fraction in selected solvents (expressed as percent by weight of resin)			
				Water	95 pct ethyl alcohol	Ethyl acetate	Benzene
1 Nylon 66 resins	1.14±0.015	475–495	Dissolves in 1 h	1.5	1.5	0.2	0.2
2 Nylon 610 resins	1.09± .015	405–425	Insoluble after 1 h	1.0	2.0	1.0	1.0
3 Nylon 66/610 resins	1.10± .015	375–395	Dissolves in 1 h	1.5	2.0	1.0	1.0
4 Nylon 6/66 resins	1.13± .015	440–460	do	2.0	2.0	1.5	1.5
5.1 Nylon 11 resins for use in articles intended for 1-time use or repeated use in contact with food.	1.04± .015	355–375	Insoluble after 1 h	.30	.35	.25	.30
5.2 Nylon 11 resins for use only: a. In articles intended for repeated use in contact with food. b. In side-seam cements for articles intended for 1-time use in contact with food and which are in compliance with sec. 175.300 of this chapter.	1.04± .015	355–375	do	.35	1.60	.35	.40
6.1 Nylon 6 resins	1.15± .015	392–446	Dissolves in 1 h	1.0	2.0	1.0	1.0
6.2 Nylon 6 resins for use only in food-contact films having an average thickness not to exceed 0.001 in.	1.15± .015	392–446	do	1.5	2.0	1.0	1.0
7. Nylon 66T resins for use only in food-contact films having an average thickness not to exceed 0.001 in.	1.16± .015	482–518	Insoluble after 1 h	1.0	1.0	.25	.25
8. Nylon 612 resins for use only in articles intended for repeated use in contact with food at temperatures not to exceed 212° F.	1.06± .015	406–420	do	.50	1.50	.50	.50
9. Nylon 12 resins for use only in food-contact films having an average thickness not to exceed 0.0016 in, intended for use in contact with nonalcoholic food under the conditions of use A (sterilization not to exceed 30 min at a temperature not to exceed 250° F), B, C, D, E, F, G, and H, of table 2 of sec. 176.170(c) of this chapter.	1.01± .015	335–355	do	1.0	2.0	1.50	1.50

(c) *Analytical methods.*—(1) *Specific gravity.* Specific gravity shall be determined by weighing a 1-gram to 5-gram sample first in air and then in freshly boiled distilled water at 23° C ±2° C.

(2) *Melting point.* The melting point shall be determined as follows: Use a hot-stage apparatus. The use of crossed nicol prisms with a microscope hot stage and reading of the thermometer when the birefringence disappears increases the accuracy. If the crossed nicol apparatus is not available, use the lowest temperature at which the sample be-

comes transparent or the sharp edges or corners of the sample become rounded as the melting point. In case of doubt as to the onset of melting, the sample is prodded with a sharp instrument. If it sticks to the heating block, it is considered to have melted. If the melting point is low, dry the sample in an oven at 85° C for 24 hours in a nitrogen atmosphere then repeat the test.

(3) *Solubility in boiling 4.2N HCl.* The test shall be run on a sample approximately the size of a ⅛-inch cube in at least 25 milliliters of 4.2 normal hydrochloric acid.

(4) *Maximum extractable fraction in selected solvents.* The procedure for determining the maximum extractable fraction of the nylon resins in selected solvents is as follows:

(i) Film should be cut with ordinary scissors into pieces of a convenient size such as ¼-inch squares, for the extraction tests described in this section. The granules of nylon molding powders are in the proper form for the extraction tests. Samples of fabricated articles such as pipe, fittings, and other similar articles must be cut to approximately the size of the molding powder. This can be done conveniently by using a small-scale commercial plastics granulator and cutting the sample through a screen having ¼-inch mesh. Fine particles should be separated from the cut resin by screening through a 20-mesh screen. The material retained on the screen is suitable for the extraction tests.

(ii) The organic solvents must be of American Chemical Society analytical reagent grade; distilled water is used. Approximately 30 grams of the prepared sample is weighed to the nearest milligram. The weighed resin is transferred to a 500-milliliter round-bottom flask equipped with a reflux condenser. Approximately 300-milliliters of solvent is added to the flask and the contents refluxed gently for 8 hours with a heating mantle. The solvent is then filtered off immediately while still hot, using a Buchner funnel approximately 5 inches in diameter, a suction flask, and a hardened filter paper (Whatman No. 50 or equivalent). The paper is wet with the solvent and a slight suction applied just before starting the filtration. The resin is washed twice with approximately 100-milliliter portions of solvent and the combined filtrate and washings are reduced to approximately 25 milliliters by evaporation at reduced pressure (50 millimeters to 100 millimeters of mercury, absolute), heating as necessary. The contents of the flask are transferred to an evaporation dish (which has been held in a vacuum desiccator over anhydrous calcium sulfate until constant weight has been attained) and carefully evaporated to dryness. The weight of the solid residue is determined by difference after holding in a vacuum desiccator over anhydrous calcium sulfate until constant weight has been attained. The percent of solids extracted is calculated by dividing the weight of the solid residue by the weight of the sample and multiplying by 100.

§ 177.1520 Olefin polymers.

The olefin polymers listed in paragraph (a) of this section may be safely used as articles or components of articles intended for use in contact with food, subject to the provisions of this section.

(a) For the purpose of this section, olefin polymers are basic polymers manufactured as described in this paragraph, so as to meet the specifications prescribed in paragraph (c) of this section, when tested by the methods described in paragraph (d) of this section.

(1) Polypropylene consists of basic polymers manufactured by the catalytic polymerization of propylene.

(2) Polyethylene consists of basic polymers manufactured by the catalytic polymerization of ethylene.

(3) Olefin basic copolymers consist of basic copolymers manufactured by the catalytic copolymerization of:

(i) Two or more of the 1-alkenes having 2 to 8 carbon atoms. Such olefin basic copolymers contain not less than 96 weight-percent of polymer units derived from ethylene and/or propylene, except that oelfin basic copolymers manufactured by the catalytic copolymerization of two or more of the monomers ethylene, propylene, butene-1,2-methylpropene-1, and 2,4,4-trimethylpentene-1 shall contain not less than 85 weight-percent of polymer units derived from ethylene and/or propylene; or

(ii) 4-Methylpentene-1 and 1-alkenes having 6 to 10 carbon atoms. Such olefin basic copolymers shall contain not less than 95 molar percent of polymer units derived from 4-methylpentene-1; or

(iii) Ethylene and propylene that may contain as modifiers not more than 5 weight-percent of total polymer units derived by copolymerization with one or more of the following monomers:

5-Ethylidine-2-norbornene.
5-Methylene-2-norbornene.

(iv) Ethylene and propylene that may contain as a modifier not more than 4.5 weight percent of total polymer units derived by copolymerization with 1,4-hexadiene.

(4) Poly(methylpentene) consists of basic polymers manufactured by the catalytic polymerization of 4-methylpentene-1.

(b) The basic olefin polymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic olefin polymers. The optional adjuvant substances required in the production of the basic olefin polymers or finished food-contact articles may include substances permitted for such use by applicable regulations in Parts 170 through 189 of this chapter, substances generally recognized as safe in food and food packaging, substances used in accordance with a prior sanction or approval, and the following:

Substance	*Limitations*
7-(2*H*-Naphtho[1,2-*d*] triazol-2-yl) - 3 - phenylcoumarin [Chemical Abstracts Service Registry No. 3333-62-8] having a melting point of 250° to 251° C and a nitrogen content of 10.7 to 11.2 percent.	For use as an optical brightener only at levels not to exceed 20 parts per million by weight of olefin polymers having a thickness of 0.025 inch or less and complying with the specifications for items 1.1, 2.1, 3.1, 3.3, and 4 of paragraph (c) of this section; and under the conditions described in § 176.170(c) of this chapter, table 2 under conditions of use E through G.

(c) Specifications:

Olefin polymers	Density	Melting point (MP) or softening point (SP) (*Degrees Centigrade*)	Maximum extractable fraction (expressed as percent by weight of polymer) in *n*-hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in xylene at specified temperatures
1.1 Polypropylene	0.880–0.913	MP:160°–180° C.	6.4 pct at reflux temperature.	9.8 pct at 25° C.
1.2 Polypropylene, noncrystalline; for use only to plasticize polyethylene described under items 2.1 and 2.2 of this table, provided that such plasticized polymers meet the maximum extractable fraction and maximum soluble fraction specifications prescribed for such basic polyethylene.	0.80–0.88			
1.3 Polypropylene, noncrystalline, for use only: To plasticize polypropylene described by item 1.1 of this table, provided that such plasticized polymers meet the maximum extractable fraction and maximum soluble fraction specifications prescribed for such basic polypropylene, and further provided that such plasticized polypropylene contacts food only of the types identified in § 176.170(c) of this chapter, table 1, under types I, II, IV-B, VI-B, VII-B, and VIII; and for use at levels not to exceed 50 pct by weight of any mixture employed as a food-contact coating provided such coatings contact food only of the types identified in § 176.170(c) of this chapter, table 1, under types I, II, IV-B, VI-B, VII-B, and VIII.	0.80–0.88	SP:115°–138° C.		

Olefin polymers	Density	Melting point (MP) or softening point (SP) (*Degrees Centigrade*)	Maximum extractable fraction (expressed as percent by weight of polymer) in n-hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in xylene at specified temperatures
2.1 Polyethylene for use in articles that contact food except for articles used for packing or holding food during cooking.	0.85 -1.00	----------	5.5 pct at 50° C	11.3 pct at 25° C.
2.2 Polyethylene for use in articles used for packing or holding food during cooking.	0.85 -1.00	----------	2.6 pct at 50° C	Do.
2.3 Polyethylene for use only as component of food-contact coatings at levels up to and including 50 percent by weight of any mixture employed as a food-contact coating.	0.85 -1.00	----------	53 pct at 50° C	75 pct at 25° C.
3.1 Olefin copolymers described in par. (a)(3)(i) of this section for use in articles that contact food except for articles used for packing or holding food during cooking.	0.85 -1.00	----------	5.5 pct at 50° C	30 pct at 25° C.
3.2 Olefin copolymers described in par. (a)(3)(i) of this section for use in articles used for packing or holding food during cooking.	0.85 -1.00	----------	2.6 pct at 50° C	Do.
3.3 Olefin copolymers described in par. (a)(3)(ii) of this section.	0.82 -0.85	MP: 235°-250° C.	6.6 pct at reflux temperature.	7.5 pct at 25° C.
3.4 Olefin copolymers, primarily noncrystalline, described in par. (a)(3)(iii) of this section provided that such olefin polymers have a minimum viscosity average molecular weight of 120,000 as determined by the method described in par. (d)(5) of this section and a minimum Mooney viscosity of 35 as determined by the method described in par. (d)(6) of this section, and further provided that such olefin copolymers contact food only of the types identified in sec. 176.170(c) of this chapter, table 1, under types I, II, III, IV-B, VI, VII, VIII, and IX.	0.85 -0.90	----------	----------	----------
3.5 Olefin copolymers, primarily noncrystalline, described in paragraph (a)(3)(iv) of this section, provided that such olefin polymers have a minimum viscosity average molecular weight of 95,600 as determined by the method described in paragraph (d)(5) of this section, and further provided that such olefin polymers are used oly in blends with olefin polymers described under items 1.1, 2.1, and 2.2 of this table at a maximum level of 25 pct by weight, ahd provided that such olefin copolymers contact food only of the types identified in § 176.170 (c) of this chapter, table 1, under types I, II, IV=B, VI, VII-B, and VII at temperatures not exceeding 190° F.	0.85-0.90	----------	----------	----------
4. Poly(methylpentene)	0.82 -0.85	MP: 235°-250° C.	6.6 pct at reflux temperature.	7.5 pct at 25° C.

(d) The analytical methods for determining whether olefin polymers conform to the specifications prescribed in this section are as follows, and are applicable to the basic polymer in film form not exceeding 4 mils in thickness. The film to be tested shall be cut into approximately 1-inch squares by any convenient method that avoids contamination by dust, dirt, or grease (NOTE: Do not touch samples with bare fingers—use forceps to hold or transfer samples).

(1) *Density.* Density shall be determined by ASTM Method D 1505.

(2) *Melting point or softening point*—(i) *Melting point.* The melting point shall be determined by ASTM Method D 2117-62T.

(ii) *Softening point.* The softening point shall be determined by ASTM Method E 28-58T.

(3) *Maximum extractable fraction in n-hexane*—(i) *Olefin Copolymers described in paragraph (a)(3)(ii) of this section, polypropylene, and poly(methylpentene).* A sample is refluxed in the solvent for 2 hours and filtered at the boiling point. The filtrate is evaporated and the total residue weighed as a measure of the solvent extractable fraction.

(a) *Apparatus.* (1) Erlenmeyer flasks, 250-milliliter, with ground joint.

(2) Condensers, Allihn, 400-millimeter jacket, with ground joint.

(3) Funnels, ribbed 75-millimeter diameter, stem cut to 40 millimeters.

(4) Funnels, Büchner type, with coarse-porosity fritted disc, 60-millimeter diameter.

(5) Bell jar for vacuum filtration into beaker.

(b) *Reagent. n*-Hexane, commercial grade, specific gravity 0.663-0.667 (20° C/20° C), boiling range 66° C-69° C, or equivalent.

(c) *Procedure.* Weigh 1 gram of sample accurately and place in a 250-milliliter Erlenmeyer flask containing two or three boiling stones. Add 100 milliliters of solvent, attach the flask to the condenser (use no grease), and reflux the mixture for 2 hours. Remove the flask from the heat, disconnect the condenser, and filter rapidly, while still hot, through a small wad of glass wool packed in a short-stem funnel into a tared 150-millimeter beaker. Rinse the flask and filter with two 10-milliliter portions of the hot solvent, and add the rinsings to the filtrate. Evaporate the filtrate on a stream bath with the aid of a stream of nitrogen. Dry the residue in a vacuum oven at 110° C for 2 hours, cool in a desiccator, and weigh to the nearest 0.0001 gram. Determine the blank on 120 milliliters of solvent evaporated in a tared 150-milliliter beaker. Correct the sample residue for this blank if significant. Calculation:

$$\frac{\text{Grams of residue}}{\text{Grams of sample}} \times 100 = \text{Percent extractable with } n\text{-hexane.}$$

(ii) *Olefin copolymers described in paragraph (a)(3)(i) of this section and polyethylene.* A sample is extracted at 50° C in the solvent for 2 hours and filtered. The filtrate is evaporated and the total residue weighed as a measure of the solvent extractable fraction.

(*a*) *Extraction apparatus.* Two-liter, straight-walled, Pyrex (or equivalent) resin kettles, fitted with three-hole ground-glass covers are most convenient for this purpose. The cover is fitted with a thermometer, a gas-tight stirrer driven by an air motor or explosion-proof electric motor, and a reflux condenser. The kettle is fitted with an electric heating mantle of appropriate size and shape, which is controlled by a variable-voltage transformer.

(*b*) *Evaporating apparatus.* Rapid evaporation of large volumes of solvent requires special precautions to prevent contamination by dust. This is facilitated by a special "gas" cover consisting of an inverted flat Pyrex crystallizing dish of an appropriate size (190 millimeters x 100 millimeters) to fit a 1-liter beaker. Through the center of the dish are sealed an inlet tube for preheated, oxygen-free nitrogen, and an outlet tube located 1 inch off center. Nitrogen is fed from the supply source through a coil of ¼-inch stainless steel tubing immersed in the same steam bath used to supply heat for solvent evaporation. All connections are made with flexible tetrafluoroethylene tubing.

(*c*) *Reagents*—(*1*) n-*Hexane.* Spectrograde *n*-hexane.

(*2*) *Nitrogen.* High-purity dry nitrogen containing less than 10 parts per million of oxygen.

(*d*) *Procedure.* Transfer 2.5 grams (accurately weighed to nearest 0.001 gram) of the polymer to the resin kettle. Add 1 liter of solvent and clamp top in position. Start water flowing through jacket of the reflux condenser and apply air pressure to the stirring motor to produce vigorous agitation. Turn on heating jacket with transformer set at a predetermined voltage to bring the temperature of the contents to 50° C within 20–25 minutes. As the thermometer reading approaches 45° C–47° C, reduce the voltage to the predetermined setting that will just maintain the temperature at 50° C. Do not overshoot the prescribed temperature. Should this occur discard the test and start afresh. Exactly 2 hours after the solvent temperature has reached 50° C, disconnect the heater, remove the resin kettle from the heating jacket, and decant the solvent, while still warm, through a coarse filter paper placed on top of a fritted-glass funnel, collecting the filtrate in a tared, glass-stoppered Erlenmeyer flask of 1-liter capacity. Determine the weight of the filtrate recovered to the nearest gram. Recovery should be at least 90 percent of the original solvent. Losses due to evaporation during heating and filtering have been found not to exceed 10 percent. Transfer about half of the solvent filtrate to a 1-liter beaker placed on an opening in the steam bath and immediately cover with the special "gas" cover, the inlet tube of which has been attached with flexible tetrafluoroethylene tubing to a source of high-purity nitrogen in series with a stainless steel heating coil immersed directly in the body of the steam bath. Maintain a positive flow of warm nitrogen gas throughout the evaporation of the solvent, adding the remainder of the filtrate from the Erlenmeyer flask as the evaporation proceeds. When the volume of the solvent has been reduced to about 50 milliliters, transfer the concentrated liquid to a previously tared weighing dish of suitable size. Wash the beaker twice with 20–30 milliliter portions of warm solvent, adding the washings to the weighing dish while continuing to evaporate the remainder of the solvent under the gas cover with its flow of warm nitrogen directed toward the center of the dish. In the event that an insoluble residue that cannot be removed with warm solvent remains in the beaker, it may be necessary to heat with a small amount of a higher boiling solvent such as benzene or toluene, transferring these washings to the weighing dish before final evaporation to dryness. Transfer the weighing dish with its residue to a vacuum desiccator, and allow it to remain overnight (at least 12 hours), after which the net weight of the dry residue is determined to the nearest 0.0001 gram. Correct the result for any solvent blank equivalent to the nonvolatile matter determined to be contained in the amount of solvents used in the test.

(*4*) *Maximum soluble fraction in xylene*—(*i*) *Olefin copolymers described in paragraph (a)(3)(ii) of this section, polypropylene, and poly(methylpentene).* A sample is dissolved completely in xylene by heating and stirring in a bottle with little free space. The solution is allowed to cool without stirring, whereupon the insoluble portion precipitates and is filtered off; the total solids content of the filtrate is then determined as a measure of the soluble fraction.

(*a*) *Apparatus.* (*1*) Pyrex (or equivalent) reagent bottle, 125-milliliter, glass-stoppered.

(*2*) Heating mantle of size for 150-milliliter beaker (or suitable aluminum block to fit the 125-milliliter bottle described in paragraph (d)(4)(i)(*a*)(*1*) of this section.

(*3*) Magnetic stirrer for use under the heating mantle (combination magnetic stirrer and hotplate may be used if aluminum block is used in place of heating mantle).

(*4*) Variable-voltage transformer, 7.5 amperes.

(*5*) Tetrafluoroethylene - resin-coated sirring bar, 1-inch long.

(*6*) Constant temperature water bath maintained at 25° C±0.5° C.

(*7*) *Aluminum* dishes, 18 millimeters x 60 millimeters, disposable.

(*8*) Funnel, Büchner type, with coarse-porosity fritted disc, 30–60 millimeter diameter.

(*b*) *Reagent.* Xylene with antioxidant. Dissolve 0.020 gram of phenyl-β-naphthylamine in 1 liter of industrial grade xylene having specific gravity 0.856–0.867 (20° C/20° C) and boiling range 123° C–160° C.

(*c*) *Procedure.* Weigh 1 to 2 grams of sample to the nearest 0.001 gram and place in a 125-milliliter Pyrex reagent bottle containing a 1-inch long tetrafluoroethylene-resin-coated stirring bar. Add 100 milliliters of solvent, set the stopper in lightly, and place the bottle in the heating mantle or aluminum block maintained at a temperature of 120° C, and stir with a magnetic stirrer until the sample is completely dissolved. Remove the bottle from the heat and allow it to cool 1 hour in the air, without stirring. Then place the bottle in a water bath maintained at 25° C ±0.5° C, and allow to stand 1 hour without stirring. Next, remove the bottle from the water bath, shake, and pour part of the contents into the coarse-porosity fritted-glass funnel. Apply suction, and draw 30–40 milliliters of filtrate through, adding more slurry to the funnel, and catching the filtrate in a large test tube. (If the slurry is hard to filter, add 10 grams of diatomaceous earth filter aid to the bottle and shake vigorously just prior to the filtration.) Pipet a suitable aliquot (preferably 20 milliliters) of the filtrate into a tared aluminum disposable dish. Place the dish on a steam bath covered with a fresh sheet of aluminum foil and invert a short-stemmed 4-inch funnel over the dish. Pass nitrogen (heated if desired) down through the funnel at a rate sufficient to just ripple the surface of the solvent. When the liquid has evaporated, place the dish in a vacuum oven at 140° C and less than 50 millimeters mercury pressure for 2 hours. Cool in a desiccator and weigh. (Note: If the residue value seems high, redry in the vacuum oven for one-half hour to ensure complete removal of all xylene solvent.) Calculation:

$$\frac{\text{Grams of residue}}{\text{Grams of sample}} \times \frac{\text{100 milliliters}}{\text{volume of aliquot in milliliters}} \times 100 = \text{Percent soluble in xylene}$$

(ii) *Olefin copolymers described in paragraph (a) (3) (i) of this section and polyethylene.* A sample is extracted in xylene at reflux temperature for 2 hours and filtered. The filtrate is evaporated and the total residue weighed as a measure of soluble fraction.

(a) *Apparatus—(1) Extraction apparatus.* Two-liter, straight-walled Pyrex (or equivalent) resin kettles, fitted with ground-glass covers, are most convenient for this purpose. The cover is equipped with a thermometer and an efficient reflux condenser. The kettle is fitted with an electric heating mantle of appropriate size and shape which is controlled by a variable-voltage transformer.

(2) *Constant temperature water bath.* It must be large enough to permit immersion of the extraction kettle and set to maintain 25° C±0.1° C.

(3) *Evaporating apparatus.* Gas cover consisting of a flat Pyrex crystallizing dish (190 millimeters x 100 millimeters) inverted to fit over a 1-liter beaker with 8-millimeter gas inlet tube sealed through center and an outlet tube 1 inch off center. The beaker with gas cover is inserted in an electric heating mantle equipped with a variable-voltage transformer. The outlet tube is attached to an efficient condenser mounted on a receiving flask for solvent recovery and having an outlet for connection to an aspirator pump. The heating mantle (with the beaker) is mounted on a magnetic stirring device. An infrared heat lamp is mounted vertically 3–4 inches above the gas cover to prevent condensation of the solvent inside the cover. Make all connections with flexible tetrafluoroethylene tubing.

(b) *Reagents—(1) Xylene.* American Chemical Society reagent grade that has been redistilled through a fractionating column to reduce the nonvolatile residue.

(2) *Nitrogen.* High-purity dry nitrogen containing less than 10 parts per million oxygen.

(c) *Procedure.* Transfer 5 grams ±0.001 gram of sample to the resin kettle, add 1,000 milliliters (840 grams) of xylene, and clamp top in position after inserting a piece of glass rod to prevent bumping during reflux. Start water flowing through the jacket of the reflux condenser and apply full voltage (115 volts) to the heating mantle. When the xylene starts to boil, reduce the voltage to a level just sufficient to maintain reflux. After refluxing for at least 2 hours, disconnect the power source to the mantle, remove the kettle, and allow to cool in air until the temperature of the contents drops to 50° C, after which the kettle may be rapidly cooled to 25° C–30° C by immersing in a cold water bath. Transfer the kettle to a constant temperature bath set to maintain 25° C ±0.1° C, and allow to equilibrate for a least 1 hour (may be left overnight if convenient). Break up any precipitated polymers that may have formed, and decant the xylene solution successively through a fast filter paper and then through a fritted-glass filter into a tared 1-liter Erlenmeyer flask, collecting only the first 450 milliliters—500 milliliters of filtrate (any attempt to collect more of the xylene solution usually results in clogging the filter and risking losses). Reweigh the Erlenmeyer flask and calculate the weight of the filtrate obtained to the nearest 0.1 gram. Transfer the filtrate, quantitatively, from the Erlenmeyer flask to the 1-liter beaker, insert the beaker in its heating mantle, add a glass-coated magnetic stirring bar, and mount the gas cover in place, connecting the inlet tube to the nitrogen source and the outlet to the condenser of the receiving flask. Start a flow of nitrogen (2 to 3 liters per minute) into the gas cover and connect an aspirator to the receiver using a free-flow rate equivalent to 6–7 liters of air per minute. With the infrared lamp on, adjust the voltage to the heating mantle to give a distillation rate of 12-13 milliliters per minute when the magnetic stirrer is revolving just fast enough to promote good boiling. When the volume of solvent in the beaker has been reduced to 30–50 milliliters, transfer the concentrated extractive to a suitable weighing dish that has been previously tared (dry). Rinse the beaker twice with 10–20 milliliter portions of fresh xylene, adding the rinsings to the weighing dish. Evaporate the remainder of the xylene on an electric hotplate set at low heat under the gas cover with a stream of nitrogen directed toward the center of the dish. Avoid any charring of the residue. Transfer the weighing dish to a vacuum desiccator at room temperature and allow to remain under reduced pressure for at least 12 hours (overnight), after which determine the net weight of the residue to the nearest 0.0001 gram. Correct the result for nonvolatile solvent blank obtained by evaporating the equivalent amount of xylene under identical conditions. Calculate the weight of residue originally present in the total weight of solvent (840 grams), using the appropriate factor based on the weight of filtrate evaporated.

(5) *Viscosity average molecular weight olefin copolymers described in paragraphs (a) (3) (iii) and (iv) of this section.* The viscosity average molecular weight shall be determined from the kinematic viscosity (ASTM Method D 445)[c] of solutions of the copolymers in solvents and at temperatures as follows:

(i) Olefin polymers described in paragraph (a) (3) (iii) of this section in decahydronaphthalene at 135° C.

(ii) Olefin polymers described in paragraph (a) (3) (iv) of this section in tetrachloroethylene at 30° C.

(6) *Mooney viscosity — olefin copolymers described in paragraph (a) (3) (iii) of this section.* Mooney viscosity is determined by ASTM Method D 1646–63, using the large rotor at a temperature of 212° F, except that a temperature of 260° F shall be used for those copolymers whose Mooney viscosity cannot be determined at 212° F. The apparatus containing the sample is warmed for 1 minute, run for 8 minutes, and viscosity measurements are then made.

(e) Olefin copolvmers described in paragraph (a) (3) (i) of this section and polyethylene, alone or in combination, may be subjected to irradiation bombardment from a source not to exceed 2.3 million volts intensity to cause molecular crosslinking of the polymers to impart desired properties, such as increased strength and increased ability to shrink when exposed to heat.

(f) The olefin polymers identified in and complying with this section, when used as components of the food-contact surface of any article that is the subject of a regulation in Parts 174, 175, 176, 177, 178, and § 179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(g) The provisions of this section are not applicable to olefin polymers identified in § 175.105 (c) (5) of this chapter and used in food-packaging adhesives complying with § 175.105 of this chapter.

§ 177.1550 Perfluorocarbon resins.

Perfluorocarbon resins may be safely used as articles or components of articles used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) Perfluorocarbon resins are produced by the homopolymerization and/or copolymerization of hexafluoropropylene and tetrafluoroethylene, to which may have been added certain optional substances to impart desired technological properties to the resins. Subject to any limitations prescribed in this section, the optional substances may include:

(1) Substances generally recognized as safe in food and food packaging.

(2) Substances the use of which is permitted under applicable regulations in this part, prior sanctions, or approvals.

(b) Perfluorocarbon resins shall conform to the specifications prescribed in paragraph (b) (1) of this section and shall meet the extractability limits prescribed in paragraph (b) (2) of this section.

(1) *Specifications—(i) Infrared identification.* Perfluorocarbon resins can be identified by their characteristic infrared spectra.

(ii) *Melt viscosity.* Perfluorocarbon resins have a melt viscosity of not less than 10^4 poises at 380° C as determined by American Society for Testing Materials Method D–1238–57T. Melt viscosity of the copolymers shall not vary more than 50 percent within ½-hour at 380° C.

(iii) *Thermal instability index.* The thermal instability index of the tetrafluoroethylene hemopolymer shall not exceed 50 as determined by American Society for Testing Materials Method D–1457–56T.

[c] Copies may be obtained from: American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.

(2) *Limitations.* Perfluorocarbon resins when extracted at reflux temperatures for 2 hours separately with distilled water, 50 percent ethanol in water, *n*-heptane, and ethyl acetate shall meet the following extractability limits:

(i) Total extractives not to exceed 0.2 milligram per square inch.

(ii) Fluoride extractives calculated as fluorine not to exceed 0.03 milligram per square inch.

§ 177.1570 Poly-1-butene resins and butene/ethylene copolymers.

The poly-1-butene resins and butene/ethylene copolymers identified in this section may be safely used as articles or components of articles intended for use in contact with food subject to the provisions of this section.

(a) *Identity.* Poly-1-butene resins are produced by the catalytic polymerization of butene-1 liquid monomer. Butene/ethylene copolymers are produced by the catalytic polymerization of 1-butene liquid monomer in the presence of small amounts of ethylene monomer so as to yield no higher than a 5 weight percent concentration of polymer units derived from ethylene in the copolymer.

(b) *Specifications and limitations.* Poly-1-butene resins and butene/ethylene copolymers shall conform to the specifications prescribed in paragraph (b) (1) of this section, and shall meet the extractability limits prescribed in paragraph (b) (2) of this section.

(1) *Specifications*—(i) *Infrared identification.* Poly-1-butene resins and butene/ethylene copolymers can be identified by their characteristic infrared spectra.

(ii) *Viscosity.* Poly-1-butene resins and the butene/ethylene copolymers have an intrinsic viscosity 1.0 to 3.2 as determined by ASTM Method D–1601.

(iii) *Density.* Poly-1-butene resins have a density of 0.904 to 0.920 gms/cm^3, and butene/ethylene copolymers have a density of 0.890 to 0.916 gms/cm^3 as determined by ASTM Method D–1505–63T.

(iv) *Melt index.* Poly-1-butene resins have a melt index of 0.1 to 24 and the butene/ethylene copolymers have a melt index of 0.1 to 20 as determined by ASTM Method D–1238, Condition E.

(2) *Limitations.* Poly-1-butene resins and butene/ethylene copolymers for use in articles that contact food, and for articles used for packing or holding food during cooking shall yield no more than the following extractables:

(i) Poly-1-butene resins and butene/ethylene copolymers may be used as articles or components of articles intended for use in contact with food, provided that the maximum extractables do not exceed 2.5 percent by weight of the polymer when film or molded samples are tested for two hours at 50° C in *n*-heptane; and provided further that the butene/ethylene copolymer contains no more than 1.5 percent by weight of polymer units derived from ethylene.

(ii) Butene/ethylene copolymers containing no more than 5 percent by weight of polymer units derived from ethylene may be used in food-contact films of no more than 1 mil thickness where such films are manufactured from this copolymer blended with polypropylene, complying with § 177.1520, provided that the finished film contain no more than 60 parts butene/ethylene copolymer and the maximum extractables of the finished film do not exceed 9.3 percent by weight of the film when extracted for two hours at 50° C, in *n*-heptane.

(iii) Poly-1-butene resins and butene/ethylene copolymers may be used as articles or components of articles intended for packaging or holding food during cooking, provided that the thickness of such polymers in the form in which they contact food shall not exceed 4 mils and yield maximum extractables of not more than 2.5 percent by weight of the polymer when films are extracted for two hours at 50° C in *n*-heptane; and provided further that the butene/ethylene copolymers contains no more than 1.5 percent by weight of polymer units derived from ethylene.

§ 177.1580 Polycarbonate resins.

Polycarbonate resins may be safely used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) Polycarbonate resins are polyesters produced by:

(1) The condensation of 4,4'-isopropylidenediphenol and carbonyl chloride to which may have been added certain optional adjuvant substances required in the production of the resins; or by

(2) The reaction of molten 4,4'-isopropylidenediphenol with molten diphenyl carbonate in the presence of the disodium salt of 4,4'-isopropylidenediphenol.

(3) The condensation of 4,4'-isopropylidenediphenol, carbonyl chloride, and 0.5 percent weight maximum of α2,α6-bis(6-hydroxy-*m*-tolyl) mesitol to which may have been added certain optional adjuvant substances required in the production of branched polycarbonate resins.

(b) The optional adjuvant substances required in the production of resins produced by the methods described in paragraph (a) (1) and (3) of this section may include substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, and the following:

List of substances:	*Limitations*
p-tert-Butylphenol	----------
Chloroform	----------
Ethylene dichloride	----------
Heptane	----------
Methylene chloride	----------
Monochlorobenzene	Not to exceed 500 p.p.m. as residual solvent in finished resin.
Pyridine	----------
Triethylamine	----------

(c) Polycarbonate resins shall conform to the specification prescribed in paragraph (c) (1) of this section and shall meet the extractives limitations prescribed in paragraph (c) (2) of this section.

(1) *Specification.* Polycarbonate resins can be identified by their characteristic infrared spectrum.

(2) *Extractives limitations.* The polycarbonate resins to be tested shall be ground or cut into small particles that will pass through a U.S. standard sieve No. 6 and that will be held on a U.S. standard sieve No. 10.

(i) Polycarbonate resins, when extracted with distilled water at reflux temperature for 6 hours, shall yield total extractives not to exceed 0.15 percent by weight of the resins.

(ii) Polycarbonate resins, when extracted with 50 percent (by volume) ethyl alcohol in distilled water at reflux temperature for 6 hours, shall yield total extractives not to exceed 0.15 percent by weight of the resins.

(iii) Polycarbonate resins, when extracted with *n*-heptane at reflux temperature for 6 hours, shall yield total extractives not to exceed 0.15 percent by weight of the resins.

§ 177.1590 Polyester elastomers.

The polyester elastomers identified in paragraph (a) of this section may be safely used as the food-contact surface of articles intended for use in contact with bulk quantities of dry food of the type identified in § 176.170(c) of this chapter, table 1, under type VIII, in accordance with the following prescribed conditions:

(a) For the purpose of this section, polyester elastomers are those produced by the ester exchange reaction when one or more of the following phthalates—dimethyl terephthalate, dimethyl orthophthalate, and dimethyl isophthalate—is made to react with alpha-hydro-omega-hydroxypoly(oxytetramethylene) and/or 1,4-butanediol such that the finished elastomer has a number average molecular weight between 20,000 and 30,000.

(b) Optional adjuvant substances employed in the production of the polyester elastomers or added thereto to impart desired technical or physical properties may include the following substances:

List of substances:	*Limitations*
4,4' - Bis(*alpha*, *alpha*-dimethylbenzyl) diphenylamine.	For use only as an antioxidant.
Tetrabutyl titanate	For use only as a catalyst.

(c) An appropriate sample of the finished polyester elastomer in the form in which it contacts food, when subjected to method 6191 in Federal Test Method Standard No. 141, using No. 50 Emery abrasive in lieu of Ottawa sand, shall exhibit an abrasion coefficient of not less than 100 liters per mil of thickness.

§ 177.1600 Polyethylene resins, carboxyl modified.

Carboxyl-modified polyethylene resins may be safely used as the food-contact

surface of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) For the purpose of this section, carboxyl-modified polyethylene resins consist of basic polymers produced when ethylene-methyl acrylate basic copolymers, containing no more than 25 weight percent of polymer units derived from methyl acrylate, are made to react in an aqueous medium with one or more of the following substances:

Ammonium hydroxide.
Calcium carbonate.
Potassium hydroxide.
Sodium hydroxide.

(b) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of § 176.170(c) of this chapter, yields total extractives in each extracting solvent not to exceed 0.5 milligram per square inch of food-contact surface as determined by the methods described in § 176.170(d) of this chapter; and if the finished food-contact article is itself the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation. In testing the finished food-contact articles, a separate test sample is to be used for each required extracting solvent.

(c) The provisions of paragraph (b) of this section are not applicable to carboxyl-modified polyethylene resins used in food-packaging adhesives complying with § 175.105 of this chapter.

§ 177.1610 Polyethylene, chlorinated.

Chlorinated polyethylene identified in this section may be safely used as articles or components of articles that contact food, except for articles used for packing or holding food during cooking, subject to the provisions of this section.

(a) For the purpose of this section, chlorinated polyethylene consists of basic polymers produced by the direct chlorination of polyethylene conforming to the density, maximum *n*-hexane extractable fraction, and maximum xylene soluble fraction specifications prescribed under item 2.1 of the table in § 177.1520(c). Such chlorinated polyethylene contains a maximum of 60 percent by weight of total chlorine, as determined by ASTM Method D 1303–55, and has a 7.0 percent maximum extractable fraction in *n*-hexane at 50° C as determined by the method described in § 177.1520(d)(3)(ii).

(b) Chlorinated polyethylene may be used in contact with all types of food, except that when used in contact with fatty food of types III, IV–A, V, VII–A, and IX described in table 1 of § 176.170(c) of this chapter, chlorinated polyethylene is limited to use only as a modifier admixed at levels not exceeding 15 weight percent in plastic articles prepared from polyvinyl chloride and/or from vinyl chloride copolymers complying with § 177.1980.

§ 177.1620 Polyethylene, oxidized.

Oxidized polyethylene identified in paragraph (a) of this section may be safely used as a component of food-contact articles, in accordance with the following prescribed conditions:

(a) Oxidized polyethylene is the basic resin produced by the mild air oxidation of polyethylene conforming to the density, maximum *n*-hexane extractable fraction, and maximum xylene soluble fraction specifications prescribed under item 2.3 of the table in § 177.1520(c). Such oxidized polyethylene has a minimum number average molecular weight of 1,200, as determined by high temperature vapor pressure osmometry, contains a maximum of 5 percent by weight of total oxygen, and has an acid value of 9 to 19.

(b) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of § 176.170(c) of this chapter, yields net acidified chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface when tested by the methods described in § 177.1330(c), except that net acidified chloroform-soluble extractives from paper and paperboard complying with § 176.170 of this chapter may be corrected for wax, petrolatum, and mineral oil as provided in § 176.170(d)(5)(iii)(*b*) of this chapter. If the finished food-contact article is itself the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by such regulations. (NOTE: In testing the finished food-contact article, use a separate test sample for each extracting solvent.)

(c) The provisions of this section are not applicable to oxidized polyethylene used as provided in §§ 175.105 and 176.210 of this chapter, and § 177.2800. The provisions of paragraph (b) of this section are not applicable to oxidized polyethylene used as provided in §§ 175.125 and 176.170(a)(5) of this chapter and § 177.1200.

§ 177.1630 Polyethylene phthalate polymers.

Polyethylene phthalate polymers identified in this section may be safely used as, or components of plastics (films, articles, or fabric) intended for use in contact with food in accordance with the following prescribed conditions:

(a) Polyethylene phthalate films consist of a base sheet of ethylene terephthalate polymer or ethylene terephthalate-isophthalate copolymers, to which have been added optional substances, either as constituents of the base sheet or as constitutents of coatings applied to the base sheet.

(b) Polyethylene phthalate articles consist of a base polymer of ethylene terephthalate polymer to which have been added optional substances, either as constituents of the base polymer or as constituents of coatings applied to the base polymer.

(c) (1) Polyethylene phthalate spunbonded nonwoven fabric consist of continuous filaments of ethylene terephthalate polymer and ethylene terephthalate-isophthalate copolymer to which may have been added optional adjuvant substances required in their preparation and finishing.

(2) The ethylene terephthalate-isophthalate copolymer component of the fabric shall not exceed 25 percent by weight. The filaments may be blended with other fibers regulated for the specific use and the spunbonded fabric may be further bonded by application of heat and/or pressure.

(3) The fabric shall be used only in accordance with paragraph (i) of this section.

(d) The quantity of any optional substance employed in the production of polyethylene phthalate plastics does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation further provided. Any substance employed in the production of polyethylene phthalate plastics that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and 179 of this chapter conforms with any specification in such regulation.

(e) Substances employed in the production of polyethylene phthalate plastics include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in polyethylene phthalate plastics and used in accordance with such sanction or approval.

(3) Substances which by regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter may be safely used as components of resinous or polymeric food-contact surfaces subject to the provisions of such regulation.

(4) Substances identified in this paragraph (d)(4) subject to the limitations prescribed:

LIST OF SUBSTANCES AND LIMITATIONS
(i) Base sheet:
Ethylene terephthalate copolymers: Prepared by the condensation of dimethyl terephthalate or terephthalic acid with ethylene glycol, modified with one or more of the following: Azelaic acid, dimethyl azelate, dimethyl sebacate, sebacic acid.
Ethylene terephthalate-isophthalate copolymers: Prepared by the condensation of dimethyl terephthalate and dimethyl isophthalate with ethylene glycol or terephthalic acid and isophthalic acid with ethylene glycol. The finished copolymers contain 77–83 weight percent of polymer units derived from ethylene terephthalate.
(ii) Base sheet and base polymer:
Ethylene terephthalate polymer: Prepared by the condensation of dimethyl terephthalate and ethylene glycol.
Ethylene terephthalate polymer: Prepared by the condensation of terephthalic acid and ethylene glycol.
(iii) Coatings:
2-Ethylhexyl acrylate copolymerized with one or more of the following: Acrylonitrile.

LIST OF SUBSTANCES AND LIMITATIONS—Continued

Methacrylonitrile.
Methyl acrylate.
Methyl methacrylate.
Itaconic acid.
Vinylidene chloride copolymerized with one or more of the following:
Methacrylic acid and its methyl, ethyl, propyl, butyl, or octyl esters.
Acrylic acid and its methyl, ethyl, propyl, butyl, or octyl esters.
Acrylonitrile.
Methacrylonitrile.
Vinyl chloride.
Itaconic acid.

(iv) Emulsifiers:

Sodium dodecylbenzenesulfonate: As an adjuvant in the application of coatings to the base sheet or base polymer.
Sodium lauryl sulfate: As an adjuvant in the application of coatings to the base sheet or base polymer.

(f) Polyethylene phthalate plastics conforming with the specifications prescribed in paragraph (f)(1) of this section are used as provided in paragraph (f)(2) of this section:

(1) *Specifications.* (i) The food contact surface, when exposed to distilled water at 250° F for 2 hours, yields chloroform-soluble extractives not to exceed 0.5 mg/in² of food contact surface exposed to the solvent; and

(ii) The food contact surface, when exposed to *n*-heptane at 150° F for 2 hours, yields chloroform-soluble extractives not to exceed 0.5 mg/in² of food contact surface exposed to the solvent.

(2) *Conditions of use.* The plastics are used for packaging, transporting, or holding food, excluding alcoholic beverages, at temperatures not to exceed 250° F.

(g) Polyethylene phthalate plastics conforming with the specifications prescribed in paragraph (g)(1) of this section are used as provided in paragraph (g)(2) of this section.

(1) *Specifications.* (i) The food contact surface meets the specifications in paragraph (f)(1) of this section; and

(ii) The food contact surface when exposed to 50 percent ethyl alcohol at 120° F for 24 hours, yields chloroform-soluble extractives not to exceed 0.5 mg/in² of food contact surface exposed to the solvent.

(2) *Conditions of use.* The plastics are used for packaging, transporting, or holding alcoholic beverages that do not exceed 50 percent alcohol by volume.

(h) Uncoated polyethylene phthalate plastics consisting of a base sheet or base polymer prepared as prescribed from substances identified in paragraphs (e)(4) (i) and (ii) of this section and conforming with the specifications prescribed in paragraph (h)(1) of this section are used as provided in paragraph (h)(2) of this section:

(1) *Specifications.* (i) The food contact surface, when exposed to distilled water at 250° F for 2 hours yields chloroform-soluble extractives not to exceed 0.02 milligram/inch² of food contact surface exposed to the solvent; and

(ii) The food contact surface, when exposed to *n*-heptane at 150° F for 2 hours, yields chloroform-soluble extractives not to exceed 0.02 milligram/inch² of food contact surface exposed to the solvent.

(2) *Conditions of use.* The plastics are used to contain foods during oven baking or oven cooking at temperatures above 250° F.

(i) Polyethylene phthalate fabric, identified in paragraph (c) of this section and conforming with the specifications prescribed in paragraph (i)(1) of this section, is used only as provided in paragraph (i)(2) of this section.

(1) *Specifications.* Chloroform-soluble extractives shall not exceed 0.2 milligram/inch² of food-contact surface when exposed to the following solvents at temperatures and times indicated:

(i) Distilled water at 212° F for 2 hours.

(ii) *n*-Heptane at 150° F for 2 hours.

(iii) 50 percent ethyl alcohol at 120° F for 24 hours.

(2) *Conditions of use.* The plastics are intended for:

(i) Dry food contact.

(ii) Bulk food (excluding alcoholic beverages) repeated use applications, including filtration, at temperatures not exceeding 212° F.

(iii) Filtration of bulk alcoholic beverages, not exceeding 50 percent alcohol by volume, at temperatures not exceeding 120° F.

§ 177.1640 Polystyrene and rubber-modified polystyrene.

Polystyrene and rubber-modified polystyrene identified in this section may be safely used as components of articles intended for use in contact with food, subject to the provisions of this section.

(a) *Identity.* For the purposes of this section, polystyrene and rubber-modified polystyrene are basic polymers manufactured as described in this paragraph so as to meet the specifications prescribed in paragraph (c) of this section when tested by the method described in paragraph (d) of this section.

(1) Polystyrene consists of basic polymers produced by the polymerization of styrene.

(2) Rubber-modified polystyrene consists of basic polymers produced by combining styrene-butadiene copolymers and/or polybutadiene with polystyrene, either during or after polymerization of the polystyrene, such that the finished basic polymers contain not less than 75 weight percent of total polymer units derived from styrene monomer.

(b) *Optional adjuvants.* The basic polymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic polymers. Such optional adjuvant substances may include substances permitted for such use by regulations in Parts 170 through 189 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) *Specifications.* (1) Polystyrene basic polymers identified in paragraph (a)(1) of this section shall contain not more than 1 weight percent of total residual styrene monomer, as determined by the method described in paragraph (d) of this section, except that when used in contact with fatty foods of types III, IV-A, V, VII-A, and IX described in table 1 of § 176.170(c) of this chapter, such polystyrene basic polymers shall contain not more than 0.5 weight percent of total residual styrene monomer.

(2) Rubber-modified polystyrene basic polymers identified in paragraph (a)(2) of this section shall contain not more than 0.5 weight percent of total residual styrene monomer, as determined by the method described in paragraph (d) of this section.

(d) *Analytical method for determination of total residual styrene monomer content*—(1) *Scope.* This method is suitable for the determination of residual styrene monomer in all types of styrene polymers.

(2) *Principle.* The sample is dissolved in methylene chloride. An aliquot of the solution is injected into a gas chromatograph. The amount of styrene monomer present is determined from the area of the resulting peak.

(3) *Apparatus*—(i) *Gas chromatograph.* Beckman GC-2A gas chromatograph with hydrogen flame detector or apparatus of equivalent sensitivity.

(ii) *Chromatograph column.* One-quarter inch outside diameter stainless steel tubing (0.028 inch wall thickness), 4 feet in length, packed with 20 percent polyethylene glycol (20,000 molecular weight) on alkaline treated 60–80 mesh firebrick.

(iii) *Recorder.* Millivolt range of 0–1, chart speed of 30 inches per hour.

(4) *Reagents.* Compressed air, purified; helium gas; hydrogen gas; methylene chloride, redistilled; and styrene monomer, redistilled.

(5) *Operating conditions for the gas chromatograph.* (i) The column is operated at a temperature of 100° C with a helium flow rate of 82 milliliters per minute.

(ii) The hydrogen burner is operated with 15 pounds per square inch of air pressure and 7 pounds per square inch of hydrogen pressure.

(iii) The attenuation of the hydrogen flame detector is set at 2×10^2.

(6) *Standardization.* (i) Prepare a standard solution by weighing accurately 15 to 20 milligrams of styrene monomer into a 2-ounce bottle containing 25.0 milliliters of methylene chloride. Cap the bottle tightly and shake to thoroughly mix the solution.

(ii) By means of a microliter syringe, inject 1 microliter of the standard solution into the gas chromatograph. Measure the area of the styrene monomer peak which emerges after approximately 12 minutes.

(7) *Procedure.* (i) Transfer 1 gram of sample (accurately weighed to the nearest 0.001 gram to a 2-ounce bottle and

add several glass beads. Pipette 25.0 milliliters of methylene chloride into the bottle. Cap the bottle tightly and place on a mechanical shaker. Shake until the polymer is completely dissolved. If any insoluble residue remains, allow the bottle to stand (or centrifuge at a low speed) until a clear supernatant layer appears.

(ii) By means of a microliter syringe, inject 3 microliters of the clear supernatant liquid into the gas chromatogarph.

(iii) Measure the area of the resulting styrene monomer peak. Compare the sample peak area with the area produced by the standard styrene monomer solution. Calculation:

$$\text{Percent residual styrene monomer} = \frac{\text{Milligrams monomer in standard} \times \text{peak area of sample}}{\text{Peak area of monomer standard} \times \text{sample weight in grams} \times 30}$$

(e) *Other specifications and limitations.* The polystyrene and rubber-modified polystyrene identified in and complying with this section, when used as components of the food-contact surface of any article that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(f) *Nonapplicability.* The provisions of this section are not applicable to polystyrene and rubber-modified polystyrene used in food-packaging adhesives complying with § 175.105 of this chapter.

§ 177.1650 Polysulfide polymer-polyepoxy resins.

Polysulfide polymer-polyepoxy resins may be safely used as the food-contact surface of articles intended for packaging, transporting, holding, or otherwise contacting dry food, in accordance with the following prescribed conditions:

(a) Polysulfide polymer-polyepoxy resins are the reaction products of liquid polysulfide polymers and polyfunctional epoxide resins, cured with the aid of tri(dimethylaminomethyl) phenol, to which have been added certain optional substances to impart desired technological properties to the resins. Subject to any limitations prescribed in this section, the optional substances may include:

(1) Substances generally recognized as safe in food and food packaging.

(2) Substances the use of which is permitted under applicable regulations in this part, prior sanctions, or approvals.

(3) Substances named in this subparagraph and further identified as required:

List of substances	*Limitations*
Bis(2-chloroethyl) formal	
Bis(dichloropropyl) formal	Cross-linking agent.
Butyl alcohol	Solvent.
Carbon black (channel process)	
Chlorinated paraffins	Cross-linking agent.
Epoxidized linseed oil	
Epoxidized soybean oil	
Epoxy resins (as listed in § 175.300(b)(3)(viii)(a) of this chapter).	
Ethylene glycol monobutyl ether	Solvent.
Magnesium chloride	
Methyl isobutyl ketone	Solvent.
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt.	
Sodium dibutyl naphthalene sulfonate	Wetting agent.
Sodium hydrosulfide	
Sodium polysulfide	
$\beta,\beta',\gamma,\gamma'$-Tetrachloro normal propyl ether	Cross-linking agent.
Titanium dioxide	
Toluene	Solvent.
Trichloroethane	Cross-linking agent.
1,2,3-Trichloropropane	Cross-linking agent.
Urea-formaldehyde resins	
Xylene	Solvent.

(b) The resins are used as the food-contact surface for dry food.

(c) An appropriate sample of the finished resin in the form in which it contacts food, when subjected to Method 6191 in Federal Test Method Standard No. 141, published in "Varnish, Lacquer, and Related Materials—Methods of Inspection and Sampling" (General Services Administration, Washington 25, D.C.), using No. 50 Emery abrasive in lieu of Ottawa sand, shall exhibit an abrasion coefficient of not less than 20 liters per mil of film thickness.

§ 177.1660 Poly(tetramethylene terephthalate).

Poly(tetramethylene terephthalate) (poly (oxytetramethyleneoxyterephthaloyl)) [Chemical Abstracts Service Registry No. 24968-12-5] identified in this section may be safely used as articles or components of articles intended to contact nonalcoholic food, in accordance with the following prescribed conditions:

(a) *Identity.* For the purpose of this section, poly(tetramethylene terephthalate) is the reaction product of dimethyl terephthalate with 1,4-butanediol to which may have been added certain optional substances to impart desired technological properties to the polymer.

(b) *Optional adjuvant substances.* Poly(tetramethylene terephthalate) identified in paragraph (a) of this section may contain optional adjuvant substances. The quantity of any optional adjuvant substance employed in the production of the polymer does not exceed the amount reasonably required to accomplish the intended technical or physical effect. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, and substances permitted under applicable regulations in this part.

(c) *Specifications.* (1) Inherent viscosity of a 0.50 percent solution of the polymer in phenol/tetrachloroethane (60/40 weight ratio) solvent is not less than 0.8 as determined using a Wagner viscometer (or equivalent) and calculated from the following equation:

$$\text{Inherent viscosity} = \frac{\text{natural logarithm of } N_r}{c}$$

where:

N_r = Ratio of flow time of the polymer solution to that of the solvent and c = polymer concentration of the test solution in grams per 100 milliliters.

(2) Poly(tetramethylene terephthalate) in the finished form in which it is to contact food shall yield total extractives as follows:

(i) Not to exceed 0.08 milligram per square inch of food contact surface when extracted for 2 hours at 250° F with distilled water.

(ii) Not to exceed 0.02 milligram per square inch of food contact surface when extracted for 2 hours at 150° F with *n*-heptane.

(iii) Not to exceed 0.04 milligram per square inch of food contact surface when extracted for 2 hours at 212° F with 3 percent aqueous acetic acid.

(d) *Conditions of use.* Articles or components of articles in which the poly(tetramethylene terephthalate) food contact surface is greater than 0.010 inch thick shall not be used at temperatures and exposure times exceeding 180° F and 24 hours, respectively.

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1)).)

§ 177.1670 Polyvinyl alcohol film.

Polyvinyl alcohol film may be safely used in contact with food of the types identified in § 176.170(c) of this chapter, table 1, under types V, VIII, and IX, in accordance with the following prescribed conditions:

(a) The polyvinyl alcohol film is produced from polyvinyl alcohol having a minimum viscosity of 4 centipoises when a 4-percent aqueous solution is tested at 20° C.

(b) The finished food-contact film for use in contact with food types V or IX, when extracted with the solvent characterizing the type of food and under the conditions of time and temperature characterizing its intended use as determined from tables 1 and 2 of § 176.170(c) of this chapter, yields total extractives not to exceed 0.5 milligram per square inch of food-contact surface when tested by ASTM Method F 34-63T.

(c) The finished food-contact film shall not be used as a component of food containers intended for use in contact with water.

§ 177.1680 Polyurethane resins.

The polyurethane resins identified in paragraph (a) of this section may be

safely used as the food-contact surface of articles intended for use in contact with bulk quantities of dry food of the type identified in § 176.170(c) of this chapter, table 1, under type VIII, in accordance with the following prescribed conditions:

(a) For the purpose of this section, polyurethane resins are those produced when one or more of the isocyanates listed in paragraph (a)(1) of this section is made to react with one or more of the substances listed in paragraph (a)(2) of this section:

(1) Isocyanates:

4,4'-Diisocyanato-3,3'-dimethylbiphenyl (bitolylene diisocyanate).
Diphenylmethane diisocyanate
Hexamethylene diisocyanate.
3-Isocyanatomethyl - 3,5,5 - trimethylcyclohexyl isocyanate.
4,4-Methylenebis(cyclohexyl isocyanate).
Toluene diisocyanate.

(2) List of substances:

Adipic acid.
1,4-Butanediol.
1,3-Butylene glycol.
2,2-Dimethyl-1,3-propanediol.
Ethylene glycol.
α-Hydro-ω-hydroxypoly(oxytetramethylene).
α,α' - (Isopropylidenedi - *p* - phenylene)bis [*omega* - hydroxypoly (oxypropylene) (3–4 moles)], average molecular weight 675.
Maleic anhydride.
α,α',α'',α'''-Neopentanetetrayltetrakis[*omega*-hydroxypoly (oxypropylene) (1-2 moles)], average molecular weight 400.
Pentaerythritol-linseed oil alcoholysis product.
Phthalic anhydride.
Polybutylene glycol.
Polyethyleneadipate modified with ethanolamine with the molar ratio of the amine to the adipic acid less than 0.1 to 1.
Poly(oxycarbonylpentamethylene).
Polyoxypropylene ethers of 4,4'-isopropylidenediphenol (containing an average of 2-4 moles of propylene oxide).
Polypropylene glycol.
α,α',α''-1,2,3-Propanetriyltris[*omega*-hydroxypoly(oxypropylene) (15-18 moles)], average molecular weight 3,000.
Propylene glycol.
α,α',α''-[Propylidynetris(methylene)] tris [*omega*-hydroxypoly (oxyphopylene) (minimum 1.5 moles)], minimum molecular weight 400.
α-[*p*(1,1,3,3-Tetramethylbutyl) - phenyl]-*omega* - hydroxypoly(oxyethylene) (5 moles), average molecular weight 425.
Trimethylol propane.

(b) Optional adjuvant substances employed in the production of the polyurethane resins or added thereto to impart desired technical or physical properties may include the following substances:

List of substances	*Limitations*
1-[(2-Aminoethyl) amino] 2-propanol	As a curing agent.
1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane ichloride.	As a preservative.
Dibutyltin diacetate	As a catalyst.
D butyltin dichloride	Do.
Dibutyltin dilaurate	Do.
N,N-Dimethyldodecylamine	Do.
N-Dodecylmorpholine	Do.
α,α'-[Isopropylidenebis[*p*-phenyleneoxy(2-hydroxytrimethylene)]bis[*omega*-hydroxypoly(oxyethylene) (136–170 moles)], average molecular weight 15,000.	As a stabilizer.
4,4'-Methylenedianiline	As a curing agent.
1,1',1''-Nitrilotri-2-propanol	Do.
2,2'-(*p*-Phenylenedioxy) diethanol	Do.
Phthalocyanine blue (C.I. pigment blue 15, C.I. No. 74160).	As a pigment.
Polyvinyl isobutyl ether	
Polyvinyl methyl ether	
Soya alkyd resin	Conforming in composition with § 175.300 of this chapter and containing litharge not to exceed that residual from its use as the reaction catalyst and creosol not to exceed that required as an antioxidant.
N,N,N',N'-Tetrakis(2-hydroxypropyl)ethylenediamine	As a curing agent.
Triethanolamine	Do.
Ultramarine blue	As a pigment.

(c) An appropriate sample of the finished resin in the form in which it contacts food, when subjected to Method 6191 in Federal Test Method Standard No. 141, using No. 50 Emery abrasive in lieu of Ottawa sand, shall exhibit an abrasion coefficient of not less than 20 liters per mil of film thickness.

§ 177.1810 Styrene block polymers.

The styrene block polymers identified in paragraph (a) of this section may be safely used as articles or as components of articles intended for use in contact with food, subject to provisions of this section.

(a) For the purpose of this section, styrene block polymers are basic polymers manufactured as described in this paragraph, so that the finished polymers meet the specifications prescribed in paragraph (b) of this section, when tested by the methods described in paragraph (c) of this section.

(1) Styrene block polymers with 1,3-butadiene are those produced by the catalytic solution polymerization of styrene and 1,3-butadiene.

(2) Styrene block polymers with 2-methyl-1,3-butadiene are those produced by the catalytic solution polymerization of styrene and 2-methyl-1,3-butadiene.

(3) Styrene block polymers with 1,3-butadiene, hydrogenated are those produced by the catalytic solution polymerization of styrene and 1,3-butadiene, and subsequently hydrogenated.

(b) Specifications:

Styrene block polymers	Molecular weight (minimum)	Solubility	Glass transition points	Maximum extractable fraction in distilled water at specified temperatures, times and thicknesses	Maximum extractable fraction in 50 pct ethanol at specified temperatures, times and thicknesses
1. Styrene block polymers with 1,3-butadiene; for use as articles or as components of articles that contact food of types I, II, IV-B, VI, VII-B, and VIII identified in table 1 in sec. 176.170(c) of this chapter under conditions of use D, E, F, and G described in table 2 in sec. 176.170(c) of this chapter.	29,000	Completely soluble in toluene.	−86° C to −80° C and 92° C to 98° C.	0.025 mg/in² of surface at reflux temperature for 30 min on a 0.075 in thick sample.	0.005 mg/in² of surface at 150° F for 2 hr on a 0.075 in thick sample.
2. Styrene block polymers with 2-methyl-1,3-butadiene; for use as articles or as components of articles that contact food of types I, II, IV-B, VI, VII-B and VIII identified in table 1 in sec. 176.170(c) of this chapter under conditions of use D, E, F, and G described in table 2 in sec. 176.170(c) of this chapter.	29,000	.....do.....	−52° C to −47° C and 92° C to 98° C.	0.01 mg/in² of surface at reflux temperature for 2 hr on a 0.028 in thick sample.	0.01 mg/in² of surface at 150° F for 2 hr on a 0.028 in thick sample.
3. Styrene block polymers with 1,3-butadiene, hydrogenated; for use as articles or as components of articles that contact food of types I, II, IV-B, VI, VII-B, and VIII identified in table 1 in sec. 176.170(c) of this chapter.	16,000	.....do.....	−50° C to −30° C and 92° C to 98° C.	0.01 mg/in² of surface at reflex temperature for 2 hr on a 0.028 in thick sample.	0.01 mg/in² of surface at 150° F for 2 hr on a 0.028 in thick sample.

(c) The analytical methods for determining whether styrene block polymers conform to the specifications prescribed in this section are as follows and are applicable to the finished polymer.

(1) *Molecular weight.* Molecular weight shall be determined by intrinsic viscosity (or other suitable method).

(2) *Glass transition points.* The glass transition points shall be determined by ASTM Method D2236–70th [6] modified by using a forced resonant vibration instead of a fixed vibration and by using frequencies of 25 to 40 cycles per second instead of 0.1 to 10 cycles per second.

(3) *Maximum extractable fractions in distilled water and 50 percent ethanol.* The maximum extractable fractions in distilled water and 50 percent ethanol shall be determined in accordance with § 176.170(d)(3) of this chapter using a sandwich form of the finished copolymer of the specified thickness and for the time and temperature specified in paragraph (b) of this section.

(d) The provisions of this section are not applicable to butadiene-styrene copolymers listed in other sections of this subpart.

(e) The provisions of this section are not applicable to styrene block polymers with 1,3-butadiene listed in § 175.105 of this chapter.

[6] Copies may be obtained from: American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.

§ 177.1820 Styrene-maleic anhydride copolymers.

Styrene-maleic anhydride copolymers identified in paragraph (a) of this section may be safely used as articles or components of articles intended for use in contact with food, subject to provisions of this section.

(a) For the purpose of this section, styrene-maleic anhydride copolymers are those produced by the polymerization of styrene and maleic anhydride so that the finished polymers meet the specifications prescribed in paragraph (b) of this section, when tested by the methods described in paragraph (c) of this section.

(b) Specifications:

Styrene-maleic anhydride copolymers	Molecular weight (minimum number average)	Residual styrene monomer	Residual maleic anhydride monomer	Maximum extractable fraction in distilled water at specified temperatures, times, and particle size	Maximum extractable fraction in *n*-heptane at specified temperatures, times, and particle size
Styrene-maleic anhydride copolymers containing not more than 15 pct maleic anhydride units by weight; for use as articles or as components of articles that contact food of types I, II, III, IV-A, IV-B, V, VI-B (except carbonated beverages), VII-A, VII-B, VIII, and IX identified in table 1 in sec. 176.170(c) of this chapter under conditions of use B, C, D, E, F, G, and H described in table 2 in sec. 176.170(c) of this chapter.	70,000	0.3 weight percent.	0.1 weight percent.	0.008 weight percent at reflux temperature for 1 hr utilizing particles of a size that will pass through a U.S. standard sieve No. 10 and will be held on a U.S. standard sieve No. 20.	0.02 weight percent at 73° F for 2 hr utilizing particles of a size that will pass through a U.S. standard sieve No. 10 and will be held on a U.S. standard sieve No. 20.

(c) The analytical methods for determining conformance with specifications for styrene-maleic anhydride copolymers prescribed in this section are as follows:

(1) *Molecular weight.* Molecular weight shall be determined by membrane osmometry.

(2) *Residual styrene monomer content.* Residual styrene monomer content shall be determined by the method described in § 177.1640(d).

(3) *Residual maleic anhydride monomer content.* Residual maleic anhydride monomer content shall be determined by a gas chromatographic method available upon request from the Commissioner of Food and Drugs.

(d) The provisions of this section are not applicable to styrene-maleic anhydride copolymers listed in other sections of this subpart.

§ 177.1830 Styrene-methyl methacrylate copolymers.

Styrene-methyl methacrylate copolymers identified in this section may be safely used as components of plastic articles intended for use in contact with food, subject to the provisions of this section.

(a) For the purpose of this section, styrene-methyl methacrylate copolymers consist of basic copolymers produced by the copolymerization of styrene and methyl methacrylate such that the finished basic copolymers contain more than 50 weight percent of polymer units derived from styrene.

(b) The finished plastic food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of intended use as determined from tables 1 and 2 of § 176.170(c) of this chapter, yields extractives not to exceed the following when tested by the methods prescribed in § 177.1010(c):

(1) Total nonvolatile extractives not to exceed 0.3 milligram per square inch of surface tested.

(2) Potassium permanganate oxidizable distilled water and 8 and 50 percent alcohol extractives not to exceed an absorbance of 0.15.

(3) Ultraviolet-absorbing distilled water and 8 and 50 percent alcohol extractives not to exceed an absorbance of 0.30.

(4) Ultraviolet-absorbing *n*-heptane extractives not to exceed an absorbance of 0.40.

§ 177.1850 Textryls.

Textryls identified in this section may be safely used as articles or components of articles intended for use in producing, manufacturing, packing, processing,

preparing, treating, packaging, transporting or holding food, subject to the provisions of this section.

(a) Textryls are nonwoven sheets prepared from natural or synthetic fibers, bonded with fibryl (Fibryl consists of a polymeric resin in fibrous form commingled with fiber to facilitate sheet formation and subsequently heat cured to fuse the fibryl and effect bonding).

(b) Textryls are prepared from the fibers, fibryls, and adjuvants identified in paragraph (c) of this section, and subject to limitations prescribed in that paragraph, provided that any substance that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specifications in such regulation for that substance as a component of polymeric resins used as food contact surfaces.

(c) The fibers, fibryls, and adjuvants permitted are as follows:

Substances	*Limitations*
(1) Fibers prepared from polyethylene terephthalate resins	Conforming with § 177.1630.
(2) Fibryls prepared from vinyl chloride-vinyl acetate copolymer	As the basic polymer.
(3) Adjuvant substance, dimethylformamide	As a solvent in the preparation of fibryl.

(d) Textryls meeting the conditions of test prescribed in paragraph (d)(1) of this section are used as prescribed in paragraph (d)(2) of this section.

(1) *Conditions of test.* Textryls, when extracted with distilled water at reflux temperature for 1 hour, yield total extractives not to exceed 1 percent.

(2) *Uses.* Textryls are used for packaging or holding food at ordinary temperatures and in the brewing of hot beverages.

§ 177.1900 Urea-formaldehyde resins in molded articles.

Urea-formaldehyde resins may be safely used as the food-contact surface of molded articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, urea-formaldehyde resins are those produced when 1 mole of urea is made to react with not more than 2 moles of formaldehyde in water solution.

(b) The resins may be mixed with refined wood pulp and the mixture may contain other optional adjuvant substances which may include the following:

List of substances	*Limitations*
Hexamethylenetetramine	For use only as polymerization-control agent.
Tetrachlorophthalic acid anhydride.	Do.
Zinc stearate	For use as lubricant.

(c) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of § 175.300(d) of this chapter, yields total extractives in each extracting solvent not to exceed 0.5 milligram per square inch of food-contact surface as determined by the methods described in § 175.300(e) of this chapter.

NOTE: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.

§ 177.1950 Vinyl chloride-ethylene copolymers.

The vinyl chloride-ethylene copolymers identified in paragraph (a) of this section may be safely used as components of articles intended for contact with food, under conditions of use D, E, F, or G described in table 2 of § 176.170 (c) of this chapter, subject to the provisions of this section.

(a) For the purpose of this section, vinyl chloride-ethylene copolymers consist of basic copolymers produced by the copolymerization of vinyl chloride and ethylene such that the finished basic copolymers meet the specifications and extractives limitations prescribed in paragraph (c) of this section, when tested by the methods described in paragraph (d) of this section.

(b) The basic vinyl chloride-ethylene copolymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic copolymers. The optional adjuvant substances required in the production of the basic vinyl chloride-ethylene copolymers may include substances permitted for such use by regulations in Parts 170 through 189 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) The vinyl chloride-ethylene basic copolymers meet the following specifications and extractives limitations:

(1) *Specifications.* (i) Total chlorine content is in the range of 53 to 56 percent as determined by any suitable analytical procedure of generally accepted applicability.

(ii) Intrinsic viscosity in cyclohexanone at 30° C is not less than 0.50 deciliter per gram as determined by ASTM Method D 1243–60.

(2) *Extractives limitations.* The following extractives limitations are determined by the methods described in paragraph (d) of this section:

(i) Total extractives do not exceed 0.10 weight-percent when extracted with *n*-heptane at 150° F for 2 hours.

(ii) Total extractives do not exceed 0.03 weight-percent when extracted with water at 150° F for 2 hours.

(iii) Total extractives obtained by extracting with water at 150° F for 2 hours contain no more than 0.5 milligram of vinyl chloride-ethylene copolymer per 100 grams of sample tested as determined from the organic chlorine content. The organic chlorine content is determined as described in paragraph (d)(3) of this section.

(d) Analytical methods: The analytical methods for determining whether vinyl chloride-ethylene basic copolymers conform to the extractives limitations prescribed in paragraph (c) of this sections are as follows and are applicable to the basic copolymers in powder form having a particle size such that 100 percent will pass through a U.S. Standard Sieve No. 40 and 80 percent will pass through a U.S. Standard Sieve No. 80:

(1) *Reagents*—(i) *Water.* All water used in these procedures shall be demineralized (deionized), freshly distilled water.

(ii) *n-Heptane.* Reagent grade, freshly distilled *n*-heptane shall be used.

(2) *Determination of total amount of extractives.* All determinations shall be done in duplicate using duplicate blanks. Approximately 400 grams of sample (accurately weighed) shall be placed in a 2-liter Erlenmeyer flask. Add 1,200 milliliters of solvent and cover the flask with aluminum foil. The covered flask and contents are suspended in a thermostated bath and are kept, with continual shaking at 150°F for 2 hours. The solution is then filtered through a No. 42 Whatman filter paper, and the filtrate is collected in a graduated cylinder. The total amount of filtrate (without washing) is measured and called *A* milliliters. The filtrate is transferred to a Pyrex (or equivalent) beaker and evaporated on a steam bath under a stream of nitrogen to a small volume (approximately 50–60 milliliters). The concentrated filtrate is then quantitatively transferred to a tared 100-milliliter Pyrex beaker using small, fresh portions of solvent and a rubber policeman to effect the transfer. The concentrated filtrate is evaporated almost to dryness on a hotplate under nitrogen, and is then transferred to a drying oven at 230° F in the case of the aqueous extract or to a vacuum oven at 150° F in the case of the heptane extract. In the case of the aqueous extract, the evaporation to constant weight is completed in 15 minutes at 230° F; and in the case of heptane extract, it is overnight under vacuum at 150° F. The residue is weighed and corrected for the solvent blank. Calculation:

$$\frac{\text{Grams of corrected residue}}{\text{Grams of sample}} \times \frac{1{,}200 \text{ milliliters}}{\text{Volume of filtrate A in milliliters}} \times 100 = \text{Total extractives expressed as percent by weight of sample.}$$

(3) *Vinyl chloride-ethylene copolymer content of aqueous extract*—(i) *Principle.* The vinyl chloride-ethylene copolymer content of the aqueous extract can be determined by determining the organic chlorine content and calculating the amount of copolymer equivalent to the organic chlorine content.

(ii) *Total organic chlorine content.* A weighed sample of approximately 400 grams is extracted with 1,200 milliliters of water at 150° F for 2 hours, filtered, and the volume of filtrate is measured (*A* milliliters) as described in paragraph (d) (2) of this section.

(*a*) A slurry of Amberlite IRA–400, or equivalent, is made with distilled water in a 150-milliliter beaker. The slurry is added to a chromatographic column until it is filled to about half its length. This should give a volume of resin of 15–25 milliliters. The liquid must not be allowed to drain below the top of the packed column.

(*b*) The column is regenerated to the basic (OH) form by slowly passing through it (10–15 milliliters per minute) 10 grams of sodium hydroxide dissolved in 200 milliliters of water. The column is washed with distilled water until the effluent is neutral to phenolphthalein. One drop of methyl red indicator is added to the *A* milliliters of filtered aqueous extract and, if on the basic side (yellow), nitric acid is added drop by drop until the solution turns pink.

(*c*) The extract is deionized by passing it through the exchange column at a rate of 10–15 milliliters per minute. The column is washed with 200 milliliters of distilled water. The deionized extract and washings are collected in a 1,500-milliliter beaker. The solution is evaporated carefully on a steam plate to a volume of approximately 50 milliliters and then transferred quantitatively, a little at a time, to a clean 22-milliliter Parr cup, also on the steam plate. The solution is evaporated to dryness. Next 0.25 gram of sucrose and 0.5 gram of benzoic acid are added to the cup. One scoop (approximately 15 grams) of sodium peroxide is then added to the cup. The bomb is assembled and ignition is conducted in the usual fashion.

(*d*) After the bomb has cooled, it is rinsed thoroughly with distilled water and disassembled. The top of the bomb is rinsed into a 250-milliliter beaker with distilled water. The beaker is placed on the steam plate. The bomb cup is placed in the beaker and carefully tipped over to allow the water to leach out the combustion mixture. After the bubbling has stopped, the cup is removed from the beaker and rinsed thoroughly. The solution is cooled to room temperature and cautiously neutralized with concentrated nitric acid by slowly pouring the acid down a stirring rod until the bubbling ceases. The solution is cooled and an equal volume of acetone is added.

(*e*) The solution is titrated with 0.005 *H* silver nitrate using standard potentiometric titration techniques with a silver electrode as indicator and a potassium nitrate modified calomel electrode as a reference electrode. An expanded scale recording titrimeter. Metrohm Potentiograph 2336 or equivalent, should be used; a complete blank must be run in duplicate.

(iii) *Calculations.*

$$\text{Milligrams of aqueous extracted copolymer per 100-gram sample} = \frac{T \times F \times 64.3}{\text{Weight of sample in grams}} \times 100.$$

where:

T = Milliliters of silver nitrate (sample minus blank) × normality of silver nitrate.

$$F = \frac{1{,}200}{\text{A (as defined above)}}$$

(e) The vinyl chloride-ethylene copolymers identified in and complying with this section, when used as components of the food-contact surface of any article that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(f) The provisions of this section are not applicable to vinyl chloride-ethylene copolymers used as provided in §§ 175.105 and 176.180 of this chapter.

§ 177.1960 Vinyl chloride-hexene-1 copolymers.

The vinyl chloride-hexene-1 copolymers identified in paragraph (a) of this section vinyl chloride-hexene-1 copolymers or as components of articles intended for use in contact with food, under conditions of use D, E, F, or G described in table 2 of § 176.170(c) of this chapter, subject to the provisions of this section.

(a) *Identity.* For the purposes of this section vinyl chloride-hexene-1 copolymers consist of basic copolymers produced by the copolymerization of vinyl chloride and hexene-1 such that the finished copolymers contain not more than 3 mole-percent of polymer units derived from hexene-1 and meet the specifications and extractives limitations prescribed in paragraph (b) of this section. The copolymers may optionally contain hydroxypropyl methylcellulose and trichloroethylene used as a suspending agent and chain transfer agent, respectively, in their production.

(b) *Specifications and limitations.* The vinyl chloride-hexene-1 basic copolymers meet the following specifications and extractives limitations:

(1) *Specifications.* (i) Total chlorine content is 53 to 56 percent as determined by any suitable analytical procedure of generally accepted applicability.

(ii) Inherent viscosity in cyclohexanone at 30° C is not less than 0.59 deciliters per gram as determined by ASTM Method D 1243–66.[6]

(2) *Extractives limitations.* The following extractives limitations are determined by the methods prescribed in § 177.1970(d).

(i) Total extractives do not exceed 0.01 weight percent when extracted with water at 150° F for 2 hours.

(ii) Total extractives do not exceed 0.30 weight percent when extracted with *n*-heptane at 150° F for 2 hours.

(c) *Other specifications and limitations.* The vinyl chloride-hexene-1 copolymers identified in and complying with this section, when used as components of the food-contact surface of any article that is subject to a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

§ 177.1970 Vinyl chloride-lauryl vinyl ether copolymers.

The vinyl chloride-lauryl vinyl ether copolymers identified in paragraph (a) of this section may be used as an article or as a component of an article intended for use in contact with food subject to the provisions of this section.

(a) *Identity.* For the purposes of this section vinyl chloride-lauryl vinyl ether copolymers consist of basic copolymers produced by the copolymerization of vinyl chloride and lauryl vinyl ether such that the finished copolymers contain not more than 3 weight-percent of polymer units derived from lauryl vinyl ether and meet the specifications and extractives limitations prescribed in paragraph (c) of this section.

(b) *Optional adjuvant substances.* The basic vinyl chloride-lauryl vinyl ether copolymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic copolymers. These optional adjuvant substances may include substances permitted for such use by regulations in Parts 170 through 189 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) *Specifications and limitations.* The vinyl chloride-lauryl vinyl ether basic copolymers meet the following specifications and extractives limitations:

(1) *Specifications.* (i) Total chlorine content is 53 to 56 percent as determined by any suitable analytical procedure of generally accepted applicability.

(ii) Inherent viscosity in cyclohexanone at 30° C is not less than 0.60 deciliter per gram as determined by ASTM Method D 1243–60.

(2) *Extractives limitations.* The following extractives limitations are determined by the method described in paragraph (d) of this section:

[6] Copies may be obtained from: American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.

(i) Total extractives do not exceed 0.03 weight-percent when extracted with water at 150° F for 2 hours.

(ii) Total extractives do not exceed 0.60 weight-percent when extracted with *n*-heptane at 150° F for 2 hours.

(d) *Analytical methods.* The analytical methods for determining total extractives are applicable to the basic copolymers in powder form having a particle size such that 100 percent will pass through a U.S. Standard Sieve No. 40 and such that not more than 10 percent will pass through a U.S. Standard Sieve No. 200.

(1) *Reagents*—(i) *Water.* All water used in these procedures shall be demineralized (deionized), freshly distilled water.

(ii) *n-Heptane.* Reagent grade, freshly distilled *n*-heptane shall be used.

(2) *Determination of total amount of extractives.* Place an accurately weighed sample of suitable size in a clean borosilicate flask, and for each gram of sample add 3 milliliters of solvent previously heated to 150° F. Maintain the temperature of the contents of the flask at 150° F for 2 hours using a hot plate while also maintaining gentle mechanical agitation. Filter the contents of the flask rapidly through No. 42 Whatman filter paper with the aid of suction. Transfer the filtrate to flat glass dishes that are warmed on a hot plate and evaporate the solvent with the aid of a stream of filtered air. When the volume of the filtrate has been reduced to 10 to 15 milliliters, transfer the filtrate to tared 50-milliliter borosilicate glass beakers and complete evaporation to a constant weight in a 140° F vacuum oven. Carry out a corresponding blank determination with each solvent. Determine the weight of the residue corrected for the solvent blank and calculate the result as percent of the initial weight of the resin sample taken for analysis.

(e) *Other specifications and limitations.* The vinyl chloride-lauryl vinyl ether copolymers identified in and complying with this section, when used as components of the food-contact surface of any article that is subject to a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, shall comply with any specifications and limitations perscribed by such regulation for the article in the finished form in which it is to contact food.

§ 177.1980 Vinyl chloride-propylene copolymers.

The vinyl chloride-propylene copolymers identified in paragraph (a) of this section may be safely used as components of articles intended for contact with food, subject to the provisions of this section.

(a) For the purpose of this section, vinyl chloride-propylene copolymers consist of basic copolymers produced by the copolymerization of vinyl chloride and propylene such that the finished basic copolymers meet the specifications and extractives limitations prescribed in paragraph (c) of this section, when tested by the methods described in paragraph (d) of this section.

(b) The basic vinyl chloride-propylene copolymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic copolymers. The optional adjuvant substances required in the production of the basic vinyl chloride-propylene copolymers may include substances permitted for such use by regulations in Parts 170 through 189 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) The vinyl chloride-propylene basic copolymers meet the following specifications and extractives limitations:

(1) *Specifications.* (i) Total chlorine content is in the range of 53 to 56 percent as determined by any suitable analytical procedure of generally accepted applicability.

(ii) Intrinsic viscosity in cyclohexanone at 30° C is not less than 0.50 deciliter per gram as determined by ASTM Method D 1243–60.

(2) *Extractives limitations.* The following extractives limitations are determined by the methods described in paragraph (d) of this section:

(i) Total extractives do not exceed 0.10 weight-percent when extracted with *n*-heptane at 150° F for 2 hours.

(ii) Total extractives do not exceed 0.03 weight-percent when extracted with water at 150° F for 2 hours.

(iii) Total extractives obtained by extracting with water at 150° F for 2 hours contain no more than 0.17 milligram of vinyl chloride-propylene copolymer per 100 grams of sample tested as determined from the organic chlorine content. For the purpose of this section, the organic chlorine content is the difference between the total chlorine and ionic chlorine contents determined as described in paragraph (d) of this section.

(d) Analytical methods: The analytical methods for determining whether vinyl chloride-propylene basic copolymers conform to the extractives limitations prescribed in paragraph (c) of this section are as follows and are applicable to the basic copolymers in powder form having a particle size such that 100 percent will pass through a U.S. Standard Sieve No. 40 and 80 percent will pass through a U.S. Standard Sieve No. 80:

(1) *Reagents.* (i) *Water.* All water used in these procedures shall be demineralized (deionized), freshly distilled water.

(ii) *n-Heptane.* Reagent grade, freshly distilled *n*-heptane shall be used.

(2) *Determination of total amount of extractives.* All determinations shall be done in duplicate using duplicate blanks. Approximately 400 grams of sample (accurately weighed) shall be placed in a 2-liter Erlenmeyer flask. Add 1,200 milliliters of solvent and cover the flask with aluminum foil. The covered flask and contents are suspended in a thermostated bath and are kept, with continual shaking, at 150° F for 2 hours. The solution is then filtered through a No. 42 Whatman filter paper, and the filtrate is collected in a graduated cylinder. The total amount of filtrate (without washing) is measured and called *A* milliliters. The filtrate is transferred to a Pyrex (or equivalent) beaker and evaporated on a steam bath under a stream of nitrogen to a small volume (approximately 50–60 milliliters). The concentrated filtrate is then quantitatively transferred to a tared 100-milliliter Pyrex beaker using small, fresh portions of solvent and a rubber policeman to effect the transfer. The concentrated filtrate is evaporated almost to dryness on a hotplate under nitrogen, and is then transferred to a drying oven at 230° F in the case of the aqueous extract or to a vacuum oven at 150° F in the case of the heptane extract. In the case of the aqueous extract the evaporation to constant weight is completed in 15 minutes at 230° F; and in the case of heptane extract, it is overnight under vacuum at 150° F. The residue is weighed and corrected for the solvent blank. Calculation:

$$\frac{\text{Grams of corrected residue}}{\text{Grams of sample}} \times \frac{1{,}200 \text{ milliliters}}{\text{Volume of filtrate } A \text{ in milliliters}} \times 100 = \text{Total extractives expressed as percent by weight of sample.}$$

(3) *Vinyl chloride-propylene copolymer content of aqueous extract*—(i) *Principle.* The vinyl chloride-propylene copolymer content of the aqueous extract can be determined by determining the organic chlorine content and calculating the amount of copolymer equivalent to the organic chlorine content. The organic chlorine content is the difference between the total chlorine content and the ionic chlorine content.

(ii) *Total chlorine content.* A weighed sample is extracted with water at 150° F for 2 hours, filtered, and the volume of filtrate is measured (*A* milliliters) as described in paragraph (d)(2) of this section. Two drops of 50 percent by weight sodium hydroxide solution are added to prevent loss of chloride from ammonium chloride, if present, and the solution is evaporated to approximately 15 milliliters. The concentrated filtrate is quantitatively transferred to a 22-milliliter Parr bomb fusion cup and gently evaporated to dryness. To the contents of the cup are added 3.5 grams of granular sodium peroxide, 0.1 gram of powdered starch, and 0.02 gram potassium nitrate; and the contents are mixed thoroughly. The bomb is assembled, water is added to the recess at the top of the bomb and ignition is conducted in the usual fashion using a Meeker burner. The heating is continued for 1 minute after the water at the top has evaporated. The bomb is quenched in water, rinsed with distilled water, and placed in a 400-milliliter beaker. The bomb cover is rinsed with water, catching the washings in the same 400-milliliter beaker. The bomb is covered with distilled water and a watch glass and heated until the melt has dissolved. The bomb is removed, rinsed, catching the rinsings

in the beaker, and the solution is acidified with concentrated nitric acid using methyl purple as an indicator. The beaker is covered with a watch glass, and the contents are boiled gently for 10–15 minutes. After cooling to room temperature the solution is made slightly alkaline with 50 percent by weight sodium hydroxide solution, then acidified with dilute (1:5) nitric acid. Then 1.5 milliliters of 2 *N* nitric acid per 100 milliliters of solution is added and the solution is titrated with 0.005 *N* silver nitrate to the equivalence potential end point using an expanded scale pH meter (Beckman Model 76, or equivalent). A complete blank must be run in duplicate. Calculation:

$$\text{Grams of sample} \times \frac{(B-C)}{\text{Volume of filtrate } A \text{ in milliliters}} \times \frac{1{,}200 \text{ milliliters}}{100} = \text{Milliequivalents of total chlorine in aqueous extract of 100 grams of sample,}$$

where:
A = volume of filtrate obtained in extraction.
B = milliliters of silver nitrate solution used in sample titration × normality of silver nitrate solution.
C = milliliters of silver nitrate solution used in blank titration × normality of silver nitrate solution.

(iii) *Ionic chlorine content.* A weighed sample is extracted with water at 150° F for 2 hours, filtered, and the volume of filtrate is measured (*A* milliliters) as in paragraph (d)(2) of this section. Two drops of 50 percent by weight sodium hydroxide solution are added and the solution is evaporated to approximately 150 milliliters. The solution is quantitatively transferred to a 250-milliliter beaker, methyl purple indicator is added, and the solution is neutralized with 0.1 *N* nitric acid. For each 100 milliliters of solution is added 1.5 milliliters of 2 *N* nitric acid. The solution is titrated with 0.005 *N* silver nitrate to the equivalence potential end point, using the expanded scale pH meter described in paragraph (d)(3)(ii) of this section. A complete blank must be run in duplicate. Calculation:

$$\frac{(D-E)}{\text{Grams of sample}} \times \frac{1{,}200 \text{ milliliters}}{\text{Volume of filtrate } A \text{ in milliliters}} \times 100 = \text{Milliequivalents of ionic chlorine in aqueous extract of 100 grams of sample,}$$

where:
A = volume of filtrate obtained in extraction.
D = milliliters of silver nitrate solution used in sample titration × normality of silver nitrate solution.
E = milliliters of silver nitrate solution used in blank titration × normality of silver nitrate solution.

(iv) *Organic chlorine content and vinyl chloride-propylene copolymer content of aqueous extract.* The organic chlorine content and the vinyl chloride propylene copolymer content of the aqueous extract is calculated as follows:

(*a*) *Organic chlorine content.* Milliequivalents of organic chlorine in aqueous extract of 100 grams of sample equal milliequivalents of total chlorine in aqueous extract of 100 grams of sample (as calculated in paragraph (d)(3)(ii) of this section) minus milliequivalents of ionic chlorine in aqueous extract of 100 grams of sample (as calculated in paragraph (d)(3)(iii) of this section).

(*b*) *Vinyl chloride-propylene copolymer content.* Milligrams of vinyl chloride-propylene copolymer in aqueous extract of 100 grams of sample equal milliequivalents of organic chlorine in aqueous extract of 100 grams of sample (as calculated in paragraph (d)(3)(iv)(*a*) of this section) multiplied by 84.5.

(NOTE: The conversion factor, 84.5, is derived from the equivalent weight of chlorine divided by the chlorine content of the heptane extractable fraction.)

(e) The vinyl chloride-propylene copolymers identified in and complying with this section, when used as components of the food-contact surface of any article that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(f) The provisions of this section are not applicable to vinyl chloride-propylene copolymers used in food-packaging adhesives complying with § 175.105 of this chapter.

Subpart C—Substances for Use Only as Components of Articles Intended for Repeated Use

§ 177.2210 Ethylene polymer, chlorosulfonated.

Ethylene polymer, chlorosulfonated as identified in this section may be safely used as an article or component of articles intended for use in contact with food, subject to the provisions of this section.

(a) Ethylene polymer, chlorosulfonated is produced by chlorosulfonation of a carbon tetrachloride solution of polyethylene with chlorine and sulfuryl chloride.

(b) Ethylene polymer, chlorosulfonated shall meet the following specifications:

(1) Chlorine not to exceed 25 percent by weight.

(2) Sulfur not to exceed 1.15 percent by weight.

(3) Molecular weight is in the range of 95,000 to 125,000.

Methods for the above specifications are available upon request from the Food and Drug Administration, Bureau of Foods, Division of Food and Color Additives (HFF-330), 200 C St., SW., Washington, DC 20204.

(c) The additive is used as the article, or a component of articles, intended for use as liners and covers for reservoirs intended for the storage of water for drinking purposes.

(d) Substances permitted by § 177.2600 may be employed in the preparation of ethylene polymers, chlorosulfonated, subject to any limitations prescribed therein.

(e) The finished ethylene copolymers, chlorosulfonated shall conform to § 177.2600 (e) and (g).

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1)))

§ 177.2250 Filters, microporous polymeric.

Microporous polymeric filters identified in paragraph (a) of this section may be safely used, subject to the provisions of this section, to remove particles of insoluble matter in producing, manufacturing, processing, and preparing bulk quantities of liquid food.

(a) Microporous polymeric filters consist of a suitably permeable, continuous, polymeric matrix of polyvinyl chloride, vinyl chloride-propylene, or vinyl chloride-vinyl acetate, in which finely divided silicon dioxide is embedded. Cyclohexanone may be used as a solvent in the production of the filters.

(b) Any substance employed in the production of microporous polymeric filters that is the subject of a regulation in Parts 170 through 189 of this chapter must conform with any specification in such regulation.

(c) Cyclohexanone when used as a solvent in the production of the filters shall not exceed 0.35 percent by weight of the microporous polymeric filters.

(d) The microporous polymeric filters may be colored by the pigments and colorants identified in § 175.300(b)(3)(xxvi) of this chapter.

(e) The temperature of food being processed through the microporous polymeric filters shall not exceed 180° F.

(f) The microporous polymeric filters shall be maintained in a sanitary manner in accordance with good manufacturing practice so as to prevent potential microbial adulteration of the food.

(g) To assure safe use of the microporous polymeric filters, the label or labeling shall include adequate directions for a pre-use treatment, consisting of washing with a minimum of 2 gallons of potable water at a temperature of 180° F for each square foot of filter, prior to the filter's first use in contact with food.

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1)))

§ 177.2260 Filters, resin-bonded.

Resin-bonded filters may be safely used in producing, manufacturing, processing, and preparing food, subject to the provisions of this section.

(a) Resin-bonded filters are prepared from natural or synthetic fibers to which have been added substances required in their preparation and finishing, and which are bonded with resins prepared by condensation or polymerization of resin-forming materials, together with adjuvant substances required in their preparation, application, and curing.

(b) The quantity of any substance employed in the production of the resin-bonded filter does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation further provided.

(c) Any substance employed in the production of resin-bonded filters that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

(d) Substances employed in the production of resin-bonded filters include the following, subject to any limitations provided:

List of Substances and Limitations

(1) *Fibers:*

Cellulose pulp.
Cotton.
Nylon. (From nylon resins complying with the provisions of applicable regulations in Subchapter B of this chapter.
Polyethylene terephthalate complying in composition with the provisions of § 177.1630; for use in inline filtration only as provided for in paragraphs (e) and (f) of this section.
Rayon (viscose).

(2) *Substances employed in fiber finishing:*

BHT.
Butyl (or isobutyl) palmitate or stearate.
2,5-Di-*tert*-butyl hydroquinone for use only in lubricant formulations for rayon fiber finishing and at a usage level not to exceed 0.1 percent by weight of the lubricant formulations.
Dimethylpolysiloxane.
4-Ethyl-4-hexadecyl morpholinium ethyl sulfate for use only as a lubricant in the manufacture of polyethylene terephthalate fibers specified in paragraph (d)(1) of this section at a level not to exceed 0.03 percent by weight of the finished fibers.
Fatty acid (C_{20}–C_{18}) diethanolamide condensates.
Fatty acids derived from animal or vegetable fats and oils, and salts of such acids, single or mixed, as follows:
Aluminum.
Ammonium.
Calcium.
Magnesium.
Potassium.
Sodium.
Triethanolamine.
Fatty acid (C_{20}—C_{18}) mono- and diesters of polyoxyethylene glycol (molecular weight 400–3,000).
Methyl esters of fatty acids (C_{20}—C_{18}).
Mineral oil.
Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740 (b) of this chapter.
Polyoxyethylene (4 mols) ethylenediamine monolauramide for use only in lubricant formulations for rayon fiber finishing and at a usage level not to exceed 10 percent by weight of the lubricant formulations.
Ricebran oil.
Titanium dioxide.

(3) *Resins:*

Acrylic polymers produced by polymerizing ethyl acrylate alone or with one or more of the monomers: Acrylic acid, acrylonitrile, *N*-methylolacrylamide, and styrene. The finished copolymers shall contain at least 70 weight percent of polymer units derived from ethyl acrylate, no more than 2 weight percent of total polymer units derived from acrylic acid, no more than 10 weight percent of total polymer units derived from acrylonitrile, no more than 2 weight percent of total polymer units derived from *N*-methylolacrylamide, and no more than 25 weight percent of total polymer units derived from styrene. For use only as provided in paragraph (m) of this section.
Melamine-formaldehyde.
Melamine-formaldehyde chemically modified with one or more of the amine catalysts identified in § 175.300(b)(3)(xiii) of this chapter.
Melamine-formaldehyde chemically modified with methyl alcohol.
Melamine-formaldehyde chemically modified with urea; for use only as provided for in paragraphs (e), (f), (g), (h), and (i) of this section.
Phenol-formaldehyde resins.
Polyvinyl alcohol.
Polyvinyl alcohol with the copolymer of acrylic acid-allyl sucrose.
Polyvinyl alcohol with melamine formaldehyde.
Polyvinyl acetate with melamine formaldehyde.
p-Toluenesulfonamide-formaldehyde chemically modified with one or more of the amine catalysts identified in § 175.300 (b)(3)(xiii) of this chapter.

(4) *Adjuvant substances:*

Dimethyl polysiloxane with methylcellulose and sorbic acid (as an antifoaming agent).
Phosphoric acid.

(5) *Colorants:*

Phthalocyanine blue (C.I. pigment blue 15, C.I. No. 74160), not to exceed 0.1 percent in thermoplastic adhesives fabricated from components complying with §§ 177.1350 and 177.1520 for use in resin-bonded filters.

(e) Resin-bonded filters conforming with the specifications of paragraph (e)(1) of this section are used as provided in paragraph (e)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to distilled water at 100° F for 2 hours, yields total extractives not to exceed 2.8 percent by weight of the filter.

(2) *Conditions of use.* It is used to filter milk or potable water at operating temperatures not to exceed 100° F.

(f) Resin-bonded filters conforming with the specifications of paragraph (f)(1) of this section are used as provided in paragraph (e)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to distilled water at 145° F for 2 hours, yields total extractives not to exceed 4 percent by weight of the filter.

(2) *Conditions of use.* It is used to filter milk or potable water at operating temperatures not to exceed 145° F.

(g) Resin-bonded filters conforming with the specifications of paragraph (g)(1) of this section are used as provided in paragraph (g)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to *n*-hexane at reflux temperature for 2 hours, yields total extractives not to exceed 0.5 percent by weight of the filter.

(2) *Conditions of use.* It is used to filter edible oils.

(h) Resin-bonded filters conforming with the specifications of paragraph (h)(1) of this section are used as provided in paragraph (h)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to distilled water at 212° F for 2 hours, yields total extractives not to exceed 4 percent by weight of the filter.

(2) *Conditions of use.* It is used to filter milk, coffee, tea, and potable water at temperatures not to exceed 212° F.

(i) Resin-bonded filters conforming with the specifications of paragraph (i)(1) of this section are used as provided in paragraph (i)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to distilled water for 2 hours at a temperature equivalent to, or higher than, the filtration temperature of the aqueous food, yields total extractives not to exceed 4 percent, by weight, of the filter.

(2) *Conditions of use.* It is used in commercial filtration of bulk quantities of nonalcoholic, aqueous foods having a pH above 5.0.

(j) Resin-bonded filters conforming with the specifications of paragraph (j)(1) of this section are used as provided in paragraph (j)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to 5 percent (by weight) acetic acid for 2 hours at a temperature equivalent to, or higher than, the filtration temperature of the aqueous food, yields total extractives not to exceed 4 percent, by weight, of the filter.

(2) *Conditions of use.* It is used in commercial filtration of bulk quantities of nonalcoholic, aqueous foods having a pH of 5.0 or below.

(k) Resin-bonded filters conforming with the specifications of paragraph (k)(1) of this section are use as provided in paragraph (k)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to 8 percent (by volume) ethyl alcohol in distilled water for 2 hours at a temperature equivalent to, or higher than, the filtration temperature of the alcoholic beverage, yields total extractives not to exceed 4 percent, by weight, of the filter.

(2) *Conditions of use.* It is used in commercial filtration of bulk quantities of alcoholic beverages containing not more than 8 percent alcohol.

(l) Resin-bonded filters conforming with the specifications of paragraph (l)(1) of this section are used as provided in paragraph (l)(2) of this section:

(1) *Total extractives.* The finished filter, when exposed to 50 percent (by volume) ethyl alcohol in distilled water for 2 hours at a temperature equivalent to, or higher than, the filtration temperature of the alcoholic beverage, yields total extractives not to exceed 4 percent, by weight, of the filter.

(2) *Conditions of use.* It is used in commercial filtration of bulk quantities of alcoholic beverages containing more than 8 percent alcohol.

(m) Resin-bonded filters fabricated from acrylic polymers as provided in paragraph (d)(3) of this section together with other substances as provided in paragraph (d), (1), (2), and (4) of this section may be used as follows:

(1) The finished filter may be used to filter milk or potable water at operating temperatures not to exceed 100° F, provided that the finished filter when exposed to distilled water at 100° F for 2 hours yields total extractives not to exceed 1 percent by weight of the filter.

(2) The finished filter may be used to filter milk or potable water at operating temperatures not to exceed 145° F, pro-

vided that the finished filter when exposed to distilled water at 145° F for 2 hours yields total extractives not to exceed 1.2 percent by weight of the filter.

(n) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

§ 177.2280 4,4'-Isopropylidenediphenol-epichlorohydrin thermosetting epoxy resins.

4,4' - Isopropylidenediphenol - epichlorohydrin thermosetting epoxy resins may be safely used as articles or components of articles intended for repeated use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The basic thermosetting epoxy resin is made by reacting 4,4'-isopropylidenediphenol with epichlorohydrin.

(b) The resin may contain one or more of the following optional substances provided the quantity used does not exceed that reasonably required to accomplish the intended effect:

Allyl glycidyl ether	As curing system additive.
Di- and tri-glycidyl ester mixture resulting from the reaction of epichlorohydrin with mixed dimers and trimers of unsaturated C_{18} monobasic fatty acids derived from animal and vegetable fats and oils.	As modifier at levels not to exceed equal parts by weight of the 4,4'-isopropylidenediphenol-epichlorohydrin basic resin and limited to use in contact with alcoholic beverages containing not more than 8 percent of alcohol.
1,2-Epoxy-3-phenoxy-propane	As curing system additive.
Glyoxal	Do.
4,4'-Isopropylidenediphenol	Do.
4,4'-Methylenedianiline	As curing system additive.
m-Phenylenediamine	Do.
Tetrahydrophthalic anhydride	Do.

(c) In accordance with good manufacturing practice, finished articles containing the resins shall be thoroughly cleansed prior to their first use in contact with food.

(d) The provisions of this section are not applicable to 4,4'-isopropylidenediphenol-epichlorohydrin resins listed in other sections of Parts 174, 175, 176, 177, 178 and 179 of this chapter.

§ 177.2410 Phenolic resins in molded articles.

Phenolic resins identified in this section may be safely used as the food-contact surface of molded articles intended for repeated use in contact with nonacid food (pH above 5.0), in accordance with the following prescribed conditions:

(a) For the purpose of this section, the phenolic resins are those produced when one or more of the phenols listed in paragraph (a)(1) of this section are made to react with one or more of the aldehydes listed in paragraph (a)(2) of this section, with or without aniline and/or anhydro-formaldehyde aniline (hexahydro-1,3,5-triphenyl-s-triazine):

(1) Phenols:

p-tert-Amylphenol.
p-tert-Butylphenol.
o-, *m*-, and *p*-Cresol.
p-Octylphenol.
Phenol.
o- and *p*-Phenylethylphenol mixture produced when phenol is made to react with styrene in the presence of sulfuric acid catalyst.

(2) Aldehydes:

Acetaldehyde.
Formaldehyde.
Paraldehyde.

(b) Optional adjuvant substances employed in the production of the phenolic resins or added thereto to impart desired technical or physical properties include the following:

Asbestos fiber	
Barium hydroxide	For use as catalyst.
Calcium stearate	For use as lubricant.
Carbon black (channel process)	
Diatomaceous earth	
Glass fiber	
Hexamethylenetetramine	For use as curing agent.
Mica	
Oxalic acid	For use as catalyst.
Zinc stearate	For use as lubricant.

(c) The finished food-contact article, when extracted with distilled water at reflux temperature for 2 hours, using a volume-to-surface ratio of 2 milliliters of distilled water per square inch of surface tested, shall meet the following extractives limitations:

(1) Total extractives not to exceed 0.15 milligram per square inch of food-contact surface.

(2) Extracted phenol not to exceed 0.005 milligram per square inch of food-contact surface.

(3) No extracted aniline when tested by a spectrophotometric method sensitive to 0.006 milligram of aniline per square inch of food-contact surface.

(d) In accordance with good manufacturing practice, finished molded articles containing the phenolic resins shall be thoroughly cleansed prior to their first use in contact with food.

§ 177.2420 Polyester resins, cross-linked.

Cross-linked polyester resins may be safely used as articles or components of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions:

(a) The cross-linked polyester resins are produced by the condensation of one or more of the acids listed in paragraph (a)(1) of this section with one or more of the alcohols or epoxides listed in paragraph (a)(2) of this section, followed by copolymerization with one or more of the cross-linking agents listed in paragraph (a)(3) of this section:

(1) Acids:

Adipic.
Fatty acids, and dimers thereof, from natural sources.
Fumaric.
Isophthalic.
Maleic.
Methacrylic.
Orthophthalic.
Sebacic.
Terephthalic.
Trimellitic.

(2) Polyols and polyepoxides:

Butylene glycol.
Diethylene glycol.
2,2-Dimethyl-1,3-propanediol.
Dipropylene glycol.
Ethylene glycol.
Glycero.
4,4' - Isopropylidenediphenol - epichlorohydrin.
Mannitol.
α-Methyl glucoside.
Pentaerythritol.
Polyoxypropylene ethers of 4,4'-isopropylidenediphenol (containing an average of 2–7.5 moles of propylene oxide).
Propylene glycol.
Sorbitol.
Trimethylol ethane.
Trimethylol propane.
2,2,4-Trimethyl-1,3-pentanediol.

(3) Cross-linking agents:

Butyl acrylate.
Butyl methacrylate.
Ethyl acrylate.
Ethylhexyl acrylate.
Methyl acrylate.
Methyl methacrylate.
Styrene.
Vinyl toluene.

(b) Optional adjuvant substances employed to facilitate the production of the resins or added thereto to impart desired technical or physical properties include the following, provided that the quantity used does not exceed that reasonably required to accomplish the intended physical or technical effect and does not exceed any limitations prescribed in this section:

List of substances	Limitations (limits of addition expressed as percent by weight of finished resin)
1. Inhibitors:	
Benzoquinone	Total not to exceed 0.08 percent.
tert-Butyl catechol	0.01 percent.
TBHQ	
Di-*tert*-butyl hydroquinone	
Hydroquinone	
2. Accelerators:	Total not to exceed 1.5 percent.
Benzyl trimethyl ammonium chloride	0.05 percent.
Calcium naphthenate	
Cobalt naphthenate	
Copper naphthenate	
N, N-Diethylaniline	0.4 percent.
N, N-Dimethylaniline	0.4 percent.
Ethylene guanidine hydrochloride	0.05 percent.
3. Catalysts:	Total not to exceed 1.5 percent, except that methyl ethyl ketone peroxide may be used as the sole catalyst at levels not to exceed 2 percent.
Azo-bis-isobutyronitrile	
Benzoyl peroxide	
tert-Butyl perbenzoate	
Chlorbenzoyl peroxide	
Cumene hydroperoxide	
Dicumyl peroxide	
Lauroyl peroxide	
p-Menthane hydroperoxide	
Methyl ethyl ketone peroxide	
4. Solvents for inhibitors, accelerators, and catalysts:	
Butyl benzyl phthalate (containing not more than 1.0 percent by weight of dibenzyl phthalate).	
Dibutyl phthalate	
Diethylene glycol	As a solvent for benzyl trimethyl ammonium chloride or ethylene guanidine hydrochloride only.
Dimethyl phthalate	
Methyl alcohol	
Styrene	
Triphenyl phosphate	
5. Reinforcements:	
Asbestos	
Glass fiber	
Polyester fiber produced by the condensation of one or more of the acids listed in paragraph (a)(1) of this section with one or more of the alcohols listed in paragraph (a)(2) of this section.	
6. Miscellaneous materials:	
Castor oil, hydrogenated	
α-Methylstyrene	
Polyethylene glycol 6000	
Silicon dioxide	
Wax, petroleum	Complying with § 178.3710 of this chapter.

(c) The cross-linked polyester resins, with or without the optional substances described in paragraph (b) of this section, and in the finished form in which they are to contact food, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of their intended use, as determined from tables 1 and 2 of § 176.170(c) of this chapter, shall meet the following extractives limitations:

(1) Net chloroform-soluble extractives not to exceed 0.1 milligram per square inch of food-contact surface tested when the prescribed food-simulating solvent is water or 8 or 50 percent alcohol.

(2) Total nonvolatile extractives not to exceed 0.1 milligram per square inch of food-contact surface tested when the prescribed food-simulating solvent is heptane.

(d) In accordance with good manufacturing practice, finished articles containing the cross-linked polyester resins shall be thoroughly cleansed prior to their first use in contact with food.

§ 177.2430 Polyether resins, chlorinated.

Chlorinated polyether resins may be safely used as articles or components of articles intended for repeated use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The chlorinated polyether resins are produced by the catalytic polymerization of 3,3-bis(chloromethyl)oxetane, and shall contain not more than 2 percent residual monomer.

(b) In accordance with good manufacturing practice, finished articles containing the chlorinated polyether resins shall be thoroughly cleansed prior to their first use in contact with food.

§ 177.2450 Polyamide-imide resins.

Polyamide-imide resins identified in paragraph (a) of this section may be safely used as components of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions:

(a) *Identity:* For the purposes of this section the polyamide-imide resins are derived from the condensation reaction of substantially equimolar parts of trimellitic anhydride and *p,p'*-diphenylmethane diisocyanate.

(b) *Specifications:* Polyamide-imide resins identified in paragraph (a) of this section shall conform to the following specifications (analytical methods for paragraph (b) (2) and (3) of this section are available upon request from the Commissioner of Food and Drugs):

(1) Nitrogen content: not less than 7.80 weight percent and not more than 8.20 weight percent, as determined by the Dumas Nitrogen Determination as set forth in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th ed., 1970, p. 123, secs. 7.017 to 7.024.[2]

[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

(2) Solution viscosity: not less than 1.200.

(3) Residual monomers, as determined by gas chromatography, in the polyamide-imide resin, heat cured at 600° F for 15 minutes: *p,p'*-diphenylmethane diisocyanate, not more than 100 parts per million; trimellitic anhydride, not more than 500 parts per million.

(c) Extractive limitations are applicable to the polyamide-imide resin in the form of films of 1 mil uniform thickness after coating and heat-curing at 600° F for 15 minutes on stainless steel plates, each having such resin-coated surface area of 100 square inches. The cured-resin film coatings shall be extracted in accordance with the method described in § 176.170(d)(3) of this chapter, using a plurality of spaced, coated stainless steel plates, exposed to the respective food simulating solvents. The resin shall meet the following extractive limitations under the corresponding extraction conditions:

(1) Distilled water at 250° F for 2 hours: Not to exceed 0.01 milligram per square inch.

(2) Three percent acetic acid at 212° F for 2 hours: Not to exceed 0.05 milligram per square inch.

(3) Fifty percent ethyl alcohol at 160° F for 2 hours: Not to exceed 0.03 milligram per square inch.

(4) *n*-Heptane at 150° F for 2 hours: Not to exceed 0.05 milligram per square inch.

(d) In accordance with good manufacturing practice, those food contact articles, having as components the polyamide-imide resins identified in paragraph (a) of this section and intended for repeated use shall be thoroughly cleansed prior to their first use in contact with food.

§ 177.2460 Poly(2,6-dimethyl-1,4-phenylene)oxide resins.

The poly(2,6-dimethyl-1,4-phenylene) oxide resins identified in paragraph (a) of this section may be used as an article or as a component of an article intended for use in contact with food subject to the provisions of this section.

(a) *Identity.* For the purposes of this section, poly(2,6 - dimethyl - 1,4-phenylene)oxide resins consist of basic resins produced by the oxidative coupling of 2,6-xylenol such that the finished basic resins meet the specifications and extractives limitations prescribed in paragraph (c) of this section.

(b) *Optional adjuvant substances.* The basic poly(2,6-dimethyl-1,4-phenylene)oxide resins identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic resins. The optional adjuvant substances required in the production of the basic poly(2,6-dimethyl - 1,4 - phenylene)oxide resins may include substances permitted for such use by regulations in Parts 170 through 189 of this chapter, substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, and the following:

List of substances	Limitations (expressed as percent by weight of finished basic resin)
Diethylamine	Not to exceed 0.16 percent as residual catalyst.
Methyl alcohol	Not to exceed 0.02 percent as residual solvent.
Toluene	Not to exceed 0.2 percent as residual solvent.

(c) *Specifications and extractives limitations.* The poly(2,6-dimethyl-1,4-phenylene) oxide basic resins meet the following:

(1) *Specifications.* Intrinsic viscosity is not less than 0.40 deciliter per gram as determined by the method described in ASTM D1243–66 modified as follows:

(i) Solvent: Chloroform, reagent grade containing 0.01 percent *tert*-butylcatechol.

(ii) Resin sample: Powdered resin obtained from production prior to molding or extrusion.

(iii) Viscometer: Cannno-Ubbelohde series 25 dilution viscometer (or equivalent).

(iv) Calculation: The calculation method used is that described in appendix A1.2.2 (ASTM Method D 1243–66) with the reduced viscosity determined for three concentration levels (0.4, 0.2, and 0.1 gram per deciliter) and extrapolated to zero concentration for intrinsic viscosity. The following formula is used for determining reduced viscosity:

$$\text{Reduced viscosity in terms of deciliters per gram} = \frac{t - t_0}{t_0 \times c},$$

Where:
t = Solution efflux time.
t_0 = Solvent efflux time.
c = Concentration of solution in terms of grams per deciliter.

(2) *Extractives limitations.* Total resin extracted not to exceed 0.02 weight-percent when extracted with *n*-heptane at 160° F for 2 hours as determined using 200 milliliters of reagent grade *n*-heptane which has been freshly distilled before use and 25 grams of poly (2,-6-dimethyl-1,4-phenylene) oxide resin. The resin as tested is in pellet form having a particle size such that 100 percent of the pellets will pass through a U.S. Standard Sieve No. 6 and 100 percent of the pellets will be held on a U.S. Standard Sieve No. 10.

(d) *Other limitations.* The poly(2,6-dimethyl-1,4-phenylene) oxide resins identified in and complying with this section, when used as components of the food-contact surface of any article that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(e) *Uses.* The poly(2,6-dimethyl-1,4-phenylene) oxide resins identified in and complying with the limitations in this section may be used as articles or components of articles intended for repeated food-contact use or as articles or components of articles intended for single-service food-contact use only under the conditions described in § 176.170(c) of this chapter, Table 2, conditions of use H.

§ 177.2470 Polyoxymethylene copolymer.

Polyoxymethylene copolymer identified in this section may be safely used as an article or component of articles intended for food-contact use in accordance with the following prescribed conditions:

(a) *Identity.* For the purpose of this section, polyoxymethylene copolymer [Chemical Abstracts Service Registry Number 30754–12–2] is the reaction product of trioxane (cyclic trimer of formaldehyde) and ethylene oxide to which may have been added certain optional substances to impart desired technological properties to the copolymer.

(b) *Optional adjuvant substances.* The polyoxymethylene copolymer identified in paragraph (a) of this section may contain optional adjuvant substances required in its production. The quantity of any optional adjuvant substance employed in the production of the copolymer does not exceed the amount reasonably required to accomplish the intended technical or physical effect. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted under applicable regulations in Parts 170 through 189 of this chapter, and the following:

(1) Stabilizers (total amount of stabilizers not to exceed 2.0 percent and amount of any one stabilizer not to exceed 1.0 percent of polymer by ceed 1.0 percent of copolymer by weight)

Calcium ricinoleate.
Cyanoguanidine.
2,2′ - Methylenebis(4 - methyl - 6 - *tert*-butylphenol).
Tetrakis [methylene (3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate)] methane.*

(2) Lubricant: N,N′Distearoylethylenediamine.

(c) *Specifications.* (1) Polyoxymethylene copolymer can be identified by its characteristic infrared spectrum.

(2) Minimum number average molecular weight of the copolymer is 20,000 as determined by a method available upon request from the Food and Drug Administration, Bureau of Foods, Division of Food and Color Additives (HFF–330), 200 C St. SW., Washington, DC 20204.

(d) *Extractive limitations.* (1) Polyoxymethylene copolymer in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food and under conditions of time and temperature as determined from Tables 1 and 2 of § 175.300(d) of this chapter, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface.

(2) Polyoxymethylene copolymer with or without the optional substances described in paragraph (b) of this section, when ground or cut into particles that pass through a U.S.A. Standard Sieve No. 6 and that are retained on a U.S.A. Standard Sieve No. 10, shall yield total extractives as follows:

(i) Not to exceed 0.20 percent by weight of the copolymer when extracted for 6 hours with distilled water at reflux temperature.

(ii) Not to exceed 0.15 percent by weight of the copolymer when extracted for 6 hours with n-heptane at reflux temperature.

(e) *Conditions of use.* (1) The polyoxymethylene copolymer is for use as articles or components of articles intended for repeated use.

(2) Use temperature shall not exceed 250° F.

(3) In accordance with good manufacturing practice, finished articles containing polyoxymethylene copolymer shall be thoroughly cleansed before their first use in contact with food.

§ 177.2480 Polyoxymethylene homopolymer.

Polyoxymethylene homopolymer identified in this section may be safely used as articles or components of articles intended for food-contact use in accordance with the following prescribed conditions:

(a) *Identity.* For the purpose of this section, polyoxymethylene homopolymer is polymerized formaldehyde [Chemical Abstracts Service Registry No. 9002–81–7]. Certain optional adjuvant substances, described in paragraph (b) of this section, may be added to impart desired technological properties to the homopolymer.

(b) *Optional adjuvant substances.* The polyoxymethylene homopolymer identified in paragraph (a) of this section may contain optional adjuvant substances in its production. The quantity of any optional adjuvant substance employed in the production of the homopolymer does not exceed the amount reasonably required to accomplish the intended effect. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted under applicable regulations in this part, and the following:

(1) *Stabilizers* (total amount of stabilizers not to exceed 1.9 percent and amount of any one stabilizer not to exceed 0.5 percent, except that Nylon 66/610/6 terpolymer may be used up to 1.5 percent of homopolymer by weight).

(i) 2,2′ - Methylenebis(4 - methyl-6-*tert*-butylphenol).

(ii) Nylon 66/610/6 terpolymer (see § 177.1500 for identification).

(iii) Tetrakis [methylene(3,5-di-*tert*-butyl - 4 - hydroxyhydrocinnamate)] methane.

(2) *Lubricant.* *N,N'*-Distearoylethylenediamine.

(3) *Molding assistant.* Polyethylene glycol 6,000.

(c) *Specifications.* (1) Polyoxymethylene homopolymer can be identified by its characteristic infrared spectrum.

(2) Minimum number average molecular weight of the homopolymer is 25,000.

(3) Density of the homopolymer is between 1.39 and 1.44 as determined by ASTM Method D1505.[1]

(4) Melting point is between 172° C and 184° C as determined by ASTM Method D2133.[2]

(d) *Extractive limitations.* (1) Polyoxymethylene homopolymer, in the finished form which is to contact food, when extracted with the solvent or solvents characterizing the type of food and under conditions of time and temperature characterizing the conditions of intended use under paragraphs (c) (3) and (d) of § 175.300 of this chapter and as limited by paragraph (e) of this section, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface.

(2) Polyoxymethylene homopolymer, with or without the optional adjuvant substances described in paragraph (b) of this section, when ground or cut into particles that pass through a U.S.A. Standard Sieve No. 6 and that are retained on a U.S.A. Standard Sieve No. 10, shall yield extractives as follows:

(i) Formaldehyde not to exceed 0.0050 percent by weight of homopolymer as determined by a method available upon request from the Food and Drug Administration, Bureau of Foods, Division of Food and Color Additives (HFF-330), 200 C St. SW., Washington, DC 20204.

(ii) Total extractives not to exceed 0.20 percent by weight of homopolymer when extracted for 6 hours with distilled water at reflux temperature and 0.15 percent by weight of homopolymer when extracted for 6 hours with *n*-heptane at reflux temperature.

(e) *Conditions of use.* (1) Polyoxymethylene homopolymer is for use as articles or components of articles intended for repeated use.

(2) Use temperatures shall not exceed 160° F and pH of aqueous foods in contact with the homopolymer shall be between 4 and 9.

(3) In accordance with good manufacturing practice, finished articles containing polyoxymethylene homopolymer shall be thoroughly cleansed prior to first use in contact with food.

§ 177.2490 Polyphenylene sulfide resins.

Polyphenylene sulfide resins (poly(1,4-phenylene sulfide) resins) may be safely used as coatings or components of coatings of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions.

(a) Polyphenylene sulfide resins consist of basic resins produced by the reaction of equimolar parts of *p*-dichlorobenzene and sodium sulfide, such that the finished resins meet the following specifications as determined by methods available upon request from the Commissioner of Food and Drugs.

(1) Sulfur content: 28.2–29.1 percent by weight of finished resin.

(2) Minimum inherent viscosity: 0.13 deciliters per gram.

(3) Maximum residual *p*-dichlorobenzene: 0.8 ppm.

(b) Subject to any limitations prescribed in Parts 170 through 189 of this chapter, the following optional substances may be added to the polyphenylene sulfide basic resins in an amount not to exceed that reasonably required to accomplish the intended physical or technical effect.

(1) Substances generally recognized as safe in food.

(2) Substances used in accordance with prior sanction or approval.

(3) Substances the use of which is permitted in coatings under regulations in Parts 170 through 189 of this chapter.

(c) The finished coatings are thermally cured at temperatures of 700° F and above.

(d) Polyphenylene sulfide resin coatings may be used in contact with food at temperatures not to exceed the boiling point of water; provided that the finished cured coating, when extracted at reflux temperatures for 8 hours separately with distilled water, 50 percent ethanol in water, and 3 percent acetic acid, yields total extractives in each extracting solvent not to exceed 0.02 milligram per square inch of surface and when extracted at reflux temperature for 8 hours with heptane yields total extractives not to exceed 0.1 milligram per square inch of surface.

(e) Polyphenylene sulfide resin coatings containing perfluorocarbon resins complying with § 177.1550 may be used in contact with food at temperatures up to and including normal baking and frying temperatures; provided that the finished cured coating, when extracted at reflux temperatures for 2 hours separately with distilled water, 50 percent ethanol in water, 3 percent acetic acid and heptane, yields total extractives in each extracting solvent not to exceed 0.2 milligram per square inch of surface and when extracted at reflux temperature for 1 hour with diphenyl ether yields total extractives not to exceed 4.5 milligrams per square inch of surface.

§ 177.2500 Polysulfone resins.

Polysulfone resins identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, polysulfone resins (poly(oxy-*p*-phenylenesulfonyl - *p* - phenyleneoxy - *p* - phenyleneisopropylidene - *p* - phenylene) resins) consist of basic resins produced when the disodium salt of 4,4'-isopropylidenediphenol is made to react with 4,4'-dichlorodiphenyl sulfone such that the finished resins have a minimum number average molecular weight of 24,000, as determined by osmotic pressure in monochlorobenzene.

(b) The basic polysulfone resins identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic resins. The optional adjuvant substances required in the production of the basic polysulfone resins may include substances described in § 174.5(d) of this chapter and the following:

List of substances	*Limitations*
Dimethyl sulfoxide	Not to exceed 50 p.p.m. as residual solvent in finished basic resin.
Monochlorobenzene	Not to exceed 500 p.p.m. as residual solvent in finished basic resin.

(c) The finished food-contact article, when extracted at reflux temperatures for 6 hours with the solvents distilled water, 50 percent (by volume) ethyl alcohol in distilled water, 3 percent acetic acid in distilled water, and *n*-heptane, yields total extractives in each extracting solvent not to exceed 0.05 milligram per square inch of food-contact surface. (NOTE: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.)

(d) In accordance with good manufacturing practice, finished food-contact articles containing the polysulfone resins shall be thoroughly cleansed prior to their first use in contact with food.

§ 177.2510 Polyvinylidene fluoride resins.

Polyvinylidene fluoride resins may be safely used as articles or components of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, the polyvinylidene fluoride resins consist of basic resins produced by the polymerization of vinylidene fluoride.

(b) The finished food-contact article, when extracted at reflux temperatures for 2 hours with the solvents distilled water, 50 percent (by volume) ethyl alcohol in distilled water, and *n*-heptane, yields total extractives in each extracting solvent not to exceed 0.01 milligram per square inch of food-contact surface tested; and if the finished food-contact article is itself the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation. (Note: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.)

(c) In accordance with good manufacturing practice, finished food-contact articles containing the polyvinylidene fluoride resins shall be thoroughly

[1] Copies may be obtained from: Division of Nutrition (HFF-260), Bureau of Foods, Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204.

[2] Copies may be obtained from: American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.

cleansed prior to their first use in contact with food.

§ 177.2600 Rubber articles intended for repeated use.

Rubber articles intended for repeated use may be safely used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The rubber articles are prepared from natural and/or synthetic polymers and adjuvant substances as described in paragraph (c) of this section.

(b) The quantity of any substance employed in the production of rubber articles intended for repeated use shall not exceed the amount reasonably required to accomplish the intended effect in the rubber article and shall not be intended to accomplish any effect in food.

(c) Substances employed in the preparation of rubber articles include the following, subject to any limitations prescribed:

(1) Substances generally recognized as safe for use in food or food packaging.

(2) Substances used in accordance with the provisions of a prior sanction or approval.

(3) Substances that by regulation in Parfts 170 through 189 of this chapter may be safely used in rubber articles, subject to the provisions of such regulation.

(4) Substances identified in this paragraph (c)(4), provided that any substance that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

(i) *Elastomers.*

Acrylonitrile-butadiene copolymer.
Butadiene-acrylonitrile-ethylene glycol dimethacrylate copolymers containing not more than 5 weight percent of polymer units derived from ethylene glycol dimethacrylate.
Butadiene-acrylonitrile-methacrylic acid copolymer.
Butadiene-styrene-methacrylic acid copolymer.
Chloroprene polymers.
Chlorotrifluoroethylene-vinylidene fluoride copolymer.
Ethylene-propylene copolymer elastomers which may contain not more than 5 weight-percent of total polymer units derived from 5-methylene-2-norbornene and/or 5-ethylidine-2-norbornene.
Ethylene-propylene-dicyclopentadiene copolymer.
Ethylene-propylene-1,4-hexadiene copolymers containing no more than 8 weight percent of total polymer units derived from 1,4-hexadiene.
Isobutylene-isoprene copolymer.
Polybutadiene.
Polyisoprene.
Polyurethane resins derived from reactions of diphenylmethane diisocyanate with adipic acid and 1,4-butanediol.
Rubber, natural.
Silicone basic polymers as described in ASTM D-1418-61T;
- Silicone (Si) elastomers containing methyl groups.
- Silicone (Psi) elastomers containing methyl and phenyl groups.
- Silicone (Vsi) elastomers containing methyl and vinyl groups.
- Silicone (Fsi) elastomers containing methyl and fluorine groups.
- Silicone (PVsi) elastomers containing phenyl, methyl, and vinyl groups.

Styrene-butadiene copolymer.
Vinylidene fluoride-hexafluoropropylene copolymers (minimum number average molecular weight 70,000 as determined by osmotic pressure in methyl ethyl ketone).
Vinylidene fluoride - hexafluoropropylene-tetrafluoroethylene copolymers (minimum number average molecular weight 100,000 as determined by osmotic pressure in methyl ethyl ketone).

(ii) *Vulcanization materials—(a) Vulcanizing agents.*

4,4'-Bis(aminocyclohexyl)methane carbamate for use only as cross-linking agent in the vulcanization of vinylidene fluoridehexafluoropropylene copolymer and vinylidene fluoride-hexafluoropropylene-tetrafluoroethylene copolymer elastomers identified under paragraph (c)(4)(i) of this section and limited to use at levels not to exceed 2.4 percent by weight of such copolymers.
Hexamethylenediamine carbamate for use only as cross-linking agent in the vulcanization of vinylidene fluoride-hexafluoropropylene copolymer and vinylidene fluoride-hexafluoropropylene-tetrafluoroethylene copolymer elastomers identified under paragraph (c)(4)(i) of this section and limited to use at levels not to exceed 1.5 percent by weight of such copolymers.
Sulfur, ground.

(b) Accelerators (total not to exceed 1.5 percent by weight of rubber product).

2-Benzothiazyl - *N,N*-diethylthiocarbamylsulfide.
Benzoyl peroxide.
1,3 - Bis(2-benzothiazolylmercaptomethyl) urea.
N-tert-Butyl-2-benzothiazole sulfenamide
Butyraldehyde-aniline resin (iodine number 670–705).
Carbon disulfide - 1,1' - methylenedipiperidine reaction product.
Copper dimethyldithiocarbamate.
N-Cyclohexyl-2-benzothiazole sulfenamide
Dibenzoyl-*p*-quinone dioxime.
Dibenzylamine.
Di-*tert*-butyl peroxide.
Dibutyl xanthogen disulfide.
2,4-Dichlorobenzoyl peroxide.
Dicumyl peroxide.
N,N-Dimethylcyclohexylamine salt of dibutyldithiocarbamic acid.
2,6-Dimethylmorpholine thiobenzothiazol.
Dipentamethylenethiuram tetrasulfide.
Diphenylguanidine.
Diphenylguanidine phthalate.
1,3-Diphenyl-2-thiourea.
2,2'-Dithiobis[benzothiazole].
4,4'-Dithiodimorpholine.
N,N'-Di-*o*-tolylguanidine.
Di-*o*-tolylguanidine salt of pyrocatecholborate.
Ethylenediamine carbamate.
Heptaldehyde-aniline resin (iodine number 430–445).
Hexamethylenetetramine.
2-Mercaptobenzothiazole
2-Mercaptothiazoline
N-Oxydiethylene - benzothiazole-2-sulfenamide.
Piperidinium pentamethylenedithiocarbamate.
Potassium pentamethylenedithiocarbamate.
p-Quinone dioxime.
Sodium dibutyldithiocarbamate.
Sodium dimethyldithiocarbamate.
Stannous oleate for use only as an accelerator for silicone elastomers.
Tetrabutylthiuram monosulfide.
Tetraethylthiuram disulfide.
(1, 1, 4, 4-Tetramethyltetramethylene) bis [*tert*-butyl peroxide].
Tetramethylthiuram monosulfide.
Thiram (tetramethylthiuram disulfide).
Triallyl cyanurate.
Triethylenetetramine.
1,3,5-Triethyl-hexahydro-*s*-triazine (triethyltrimethylenetriamine).
Triphenylguanidine.
Zinc butyl xanathate.
Zinc dibenzyl dithiocarbamate.
Zinc dibutyldithiocarbamate.
Zinc diethyldithiocarbamate.
Zinc 2-mercaptobenzothiazole.
Ziram (zinc dimethyldithiocarbamate)

(c) Retarders (total not to exceed 10 percent of weight of rubber product).

Cyanoguanidine.
Phthalic anhydride.
Salicylic acid.

(d) Activators (total not to exceed 5 percent by weight of rubber product except magnesium oxide may be used at higher levels).

Diethylamine.
Fatty acid amines, mixed.
Fatty acids.
Magnesium carbonate.
Magnesium oxide, light and heavy.
Oleic acid, dibutylamine salt (dibutylammonium oleate).
Stannous chloride.
Tall oil fatty acids.
Tetrachloro-*p*-benzoquinone
Triethanolamine
Zinc salts of fatty acids.

(iii) *Antioxidants and antiozonants (total not to exceed 5 percent by weight of rubber product).*

Aldol-*α*-naphthylamine.
Alkylated (C_4 and/or C_6) phenols.
BHT (butylated hydroxytoluene).
Butylated, styrenated cresols identified in § 178.2010(b) of this chapter.
4,4'-Butylidinebis(6-*tert*-butyl-*m* - cresol)
N - Cyclohexyl-*N'* - phenylphenylenediamine
p,p'-Diaminodiphenylmethane.
2,5-Di-*tert*-amylhydroquinone.
Diaryl-*p*-phenylenediamine, where the aryl group may be phenyl, tolyl, or xylyl.
2,6-Di-*tert*-butyl-*p*-phenylphenol.
1,2-Dihydro-2,2,4 - trimethyl - 6-dodecylquinoline.
1,2-Dihydro-2,2,4 - trimethyl - 6 - ethoxyquinoline.
1,2-Dihydro-2,2,4 - trimethyl - 6 - phenylquinoline.
4,4'-Dimethoxydiphenylamine.
4,6-Dinonyl-*o*-cresol.
N,N'-Dioctyl-*p*-phenylenediamine.
Diphenylamine-acetone resin.
Diphenylamine - acetone - formaldehyde resin.
N,N'-Diphenylethylenediamine.
N,N'-Disalicylalpropylenediamine.
N,N'-Di-*o*-tolylethylenediamine.
Hydroquinone monobenzyl ether.
Isopropoxydiphenylamine.
N - Isopropyl-*N'*-phenyl-*p*-phenylenediamine.
2,2' - Methylenebis(6 - *tert*-butyl-4-ethylphenol).
2,2' - Methylenebis(4 - methyl - 6 - *tert*-butylphenol).
2,2'-Methylenebis(4-methyl - 6 - nonylphenol).
2,2' - Methylenebis(4 - methyl - 6 - *tert*-octylphenol).
Monooctyl- and dioctyldiphenylamine.

N,N'-Di-β-naphthyl-*p*-phenylenediamine.
Phenyl-α-naphthylamine.
Phenyl-β-naphthylamine.
Phenyl-β-naphthylamine-acetone aromatic amine resin (average molecular weight 600; nitrogen content 5.3 percent).
o- and *p*-Phenylphenol.
Polybutylated (mixture) 4,4'-isopropylidenediphenol.
Sodium pentachlorophenate.
Styrenated cresols produced when 2 moles of styrene are made to react with 1 mole of a mixture of phenol and *o*-, *m*-, and *p*-cresols so that the final product has a Brookfield viscosity at 25° C of 1400 to 1700 centipoises.
Styrenated phenol.
4,4'-Thiobis (6-*tert*-butyl-*m*-cresol).
Toluene-2,4-diamine.
N-*o*-Tolyl-*N'*-phenyl-*p*-phenylenediamine.
p(*p*-Tolylsulfanilamide) diphenylamine.
Tri(mixed mono- and dinonylphenyl) phosphite.
Tri(nonylphenyl) phosphite-formaldehyde resins produced when 1 mole of tri(nonylphenyl) phosphite is made to react with 1.4 moles of formaldehyde or produced when 1 mole of nonylphenol is made to react with 0.36 mole of formaldehyde and the reaction product is then further reacted with 0.33 mole of phosphorus trichloride. The finished resins have a minimum viscosity of 20,000 centipoises at 25° C, as determined by LV-series Brookfield viscometer (or equivalent) using a No. 4 spindle at 12 r.p.m., and have an organic phosphorus content of 4.05 to 4.15 percent by weight.

(iv) *Plasticizers (total not to exceed 30 percent by weight of rubber product).*

n-Amyl *n*-decyl phthalate.
Butylacetyl ricinoleate.
n-Butyl ester of tall oil fatty acids.
Butyl laurate.
Butyl oleate.
Butyl stearate.
Calcium stearate.
Castor oil.
Coumarone-indene resins.
2,2'-Dibenzamidodiphenyl disulfide.
Dibenzyl adipate.
Dibutoxyethoxyethyl adipate.
Dibutyl phthalate.
Dibutyl sebacate.
Didecyl adipate.
Didecyl phthalate.
Diisodecyl adipate.
Diisodecyl phthalate.
Diisooctyl adipate.
Diisooctyl sebacate.
Dioctyl adipate.
Dioctyl phthalate.
Dioctyl sebacate.
Dipentene resin.
Diphenyl ketone.
Fatty acids.
Fatty acids, hydrogenated.
Isooctyl ester of tall oil fatty acids.
Lanolin.
α-Methylstyrene-vinyltoluene copolymer resins (molar ratio 1 α-methylstyrene to 3 vinyltoluene).
Mineral oil.
Montan wax.
n-Octyl *n*-decyl adipate.
n-Octyl *n*-decyl phthalate.
Petrolatum.
Petroleum hydrocarbon resin (cyclopentadiene type), hydrogenated.
Petroleum hydrocarbon resin (produced by the homo- and copolymerization of dienes and olefins of the aliphatic, alicyclic, and monobenzenoid arylalkene types from distillates of cracked petroleum stocks.)
Petroleum hydrocarbon resin (produced by the catalytic polymerization and subsequent hydrogenation of styrene, vinyltoluene, and indene types from distillates of cracked petroleum stocks).
Petroleum oil, sulfonated.
Phenol-formaldehyde resin.
Pine tar.
Polybutene.
Polystyrene.
Propylene glycol.
n-Propyl ester of tall oil fatty acids.
Rapeseed oil vulcanized with rubber maker's sulfur.
Rosins and rosin derivatives identified in § 175.105(c)(5) of this chapter.
Soybean oil vulcanized with rubber makers' sulfur.
Styrene-acrylonitrile copolymer.
Terpene resins.
Triethylene glycol dicaprate.
Triethylene glycol dicaprylate.
Waxes, petroleum.
Xylene (or toluene) alkylated with dicyclopentadiene.
Zinc 2-benzamidothiophenate.

(v) *Fillers.*

Aluminum hydroxide.
Aluminum silicate.
Asbestos fiber, chrysotile or crocidolite.
Barium sulfate.
Carbon black (channel process or furnace combustion process; total carbon black not to exceed 50 percent by weight of rubber product; furnace combustion black content not to exceed 10 percent by weight of rubber products intended for use in contact with milk or edible oils).
Cork.
Cotton (floc, fibers, fabric).
Mica.
Nylon (floc, fibers, fabric).
Silica.
Titanium dioxide.
Zinc carbonate.
Zinc sulfide.

(vi) *Colors (total not to exceed 10 percent by weight of rubber product).*

Chrome oxide (Cr_2O_3).
C.I. pigment red 38, C.I. No. 21120.
Iron oxide.
Phthalocyanine.
Phthalocyanine blue (C.I. pigment blue 15, C.I. No. 74160).
Titanium dioxide.
Ultramarine blue.
Zinc chromate.

(vii) *Lubricants (total not to exceed 2 percent by weight of rubber product).*

Polyethylene.
Sodium stearate.

(viii) *Emulsifiers.*

Fatty acid salts, sodium or potassium.
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt.
Rosins and rosin-derivatives identified in § 175.105(c)(5) of this chapter.
Sodium decylbenzenesulfonate.
Sodium dodecylbenzenesulfonate.
Sodium lauryl sulfate.
Tall oil mixed soap (calcium, potassium, and sodium).

(ix) *Miscellaneous (total not to exceed 5 percent by weight of rubber product).*

Animal glue as described in § 178.3120 of this chapter.
Azodicarbonamide as chemical blowing agent.
2-Anthraquinone sulfonic acid sodium salt for use only as polymerization inhibitor in chloroprene polymers and not to exceed 0.03 percent by weight of the chloroprene polymers.
n-Butyllithium for use only as polymerization catalyst for polybutadiene.
4-*tert*-Butyl-*o*-thiocresol as peptizing agent.
tert-Butyl peracetate.
p-*tert*-Butylpyrocatechol.
Dialkyl (C_{12}–C_{18}) dimethylammonium chloride for use only as a flocculating agent in the manufacture of silica.
Di- and triethanolamine.
Diethyl xanthogen disulfide.
Dodecyl mercaptan isomers, single or mixed.
2-Ethoxyethanol.
Iodoform.
p-Menthane hydroperoxide.
α-(*p*-Nonylphenyl) - *omega* - hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters, barium salt; the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content averages 9 moles; for use only as residual polymerization emulsifier at levels not to exceed 0.7 percent by weight of ethylene-propylene-1,4-hexadiene copolymers identified under paragraph (c)(4) (i) of this section.
4,4'-Oxybis(benzenesulfonhydrazide) as chemical blowing agent.
Phenothiazine.
Potassium persulfate.
Sodium formaldehyde sulfoxylate.
Sodium polysulfide.
Sodium nitrite.
Sodium salt of ethylenediamine tetraacetic acid and glycine.
Sodium sulfide.
Styrene monomer.
Tall oil.
Thioxylenols as peptizing agents.
Tridecyl mercaptan.
Zinc 4-*tert*-butylthiophenate as peptizing agent.

(d) Rubber articles intended for use with dry food are so formulated and cured under conditions of good manufacturing practice as to be suitable for repeated use.

(e) Rubber articles intended for repeated use in contact with aqueous food shall meet the following specifications: The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with distilled water at reflux temperature, shall yield total extractives not to exceed 20 milligrams per square inch during the first 7 hours of extraction, nor to exceed 1 milligram per square inch during the succeeding 2 hours of extraction.

(f) Rubber articles intended for repeated use in contact with fatty foods shall meet the following specifications: The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with *n*-hexane at reflux temperature, shall yield total extractives not to exceed 175 milligrams per square inch during the first 7 hours of extraction, nor to exceed 4 milligrams per square inch during the succeeding 2 hours of extraction.

(g) In accordance with good manufacturing practice finished rubber articles intended for repeated use in contact with food shall be thoroughly

cleansed prior to their first use in contact with food.

(h) The provisions of this section are not applicable to rubber nursing-bottle nipples.

(i) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

§ 177.2710 Styrene-divinylbenzene resins, cross-linked.

Styrene - divinylbenzene cross - linked copolymer resins may be safely used as articles or components of articles intended for repeated use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The resins are produced by the copolymerization of styrene with divinylbenzene.

(b) The resins meet the extractives limitations prescribed in this paragraph:

(1) The resins to be tested are ground or cut into small particles that will pass through a U.S. standard sieve No. 3 and that will be held on a U.S. standard sieve No. 20.

(2) A 100-gram sample of the resins, when extracted with 100 milliliters of ethyl acetate at reflux temperature for 1 hour, yields total extractives not to exceed 1 percent by weight of the resins.

(c) In accordance with good manufacturing practice, finished articles containing the resins shall be thoroughly cleansed prior to their first use in contact with food.

§ 177.2800 Textiles and textile fibers.

Textiles and textile fibers may safely be used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The textiles and textile fibers are prepared from one or more of the fibers identified in paragraph (d) of this section and from certain other adjuvant substances required in the production of the textiles or textile fibers or added to impart desired properties.

(b) The quantity of any adjuvant substance employed in the production of textiles or textile fibers does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation further provided.

(c) Any substance employed in the production of textiles or textile fibers that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

(d) Substances employed in the production of or added to textiles and textile fibers may include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in textiles and textile fibers and used in accordance with such sanction or approval.

(3) Substances generally recognized as safe for use in cotton and cotton fabrics used in dry-food packaging.

(4) Substances that by regulation in this part may safely be used in the production of or as a component of textiles or textile fibers and subject to provisions of such regulation.

(5) Substances identified in this paragraph (d)(5), subject to such limitations as are provided:

List of substances	*Limitation*
(i) Fibers:	
Cotton	
Rayon	
(ii) Adjuvant substances:	
Aluminum stearate	
4,4'-Bis(4-anilino-6-diethanolamine-*s*-triazin-2-ylamino)-2,2'-stilbene-disulfonic acid, disodium salt.	For use as colorant only.
4,4'-Bis(4-anilino-6-methylethanolamine-*s*-triazin-2-ylamino)-2,2'-stilbene-disulfonic acid, disodium salt.	
Borax	For use as preservative only.
Butyl-acetyl ricinoleate	
Di-*tert*-butyl hydroquinone	
Dimethylpolysiloxane	
Ethylenediaminetetraacetic acid, sodium salt	
4-Ethyl-4-hexadecyl morpholinium ethyl sulfate	For use only as a lubricant in the manufacture of polyethylene terephthalate fibers specified in paragraph (c)(5)(i) of this section at a level not to exceed 0.03 percent by weight of the finished fibers.
Eugenol	
Fats, oils, fatty acids, and fatty alcohols derived from castor, coconut, cottonseed, fish, mustardseed, palm, peanut, rapeseed, ricebran, soybean, sperm, and tall oils and tallow.	
Fats, oils, fatty acids, and fatty alcohols described in the preceding item reacted with one or more of the following substances:	
n-Butyl and isobutyl alcohol	
Diethylene glycol	
Diethanolamine	
Glycerol	
Hexylene glycol (2-methyl-2,4-pentanediol)	
Hydrogen	
Isopropyl alcohol	
Methyl alcohol	
Oxygen	
Polyethylene glycol (molecular weight 400—3,000)	
Potassium hydroxide	
Propylene glycol	
Sodium hydroxide	
Sulfuric acid	
Formaldehyde	For use as preservative only.
Glyceryl mono-12-hydroxystearate	
2-(9-Heptadecenyl)-1-[2-(10-octadecenamido)ethyl]-2-imidazolinium ethyl sulfate.	
Hexylene glycol (2-methyl,2,4-pentanediol)	
Isobutyl alcohol	
Isopropyl alcohol	
Kerosene	
Methyl ester of sulfated ricebran oil	
Mineral oil	For use only at a level not to exceed 0.15 percent by weight of finished fibers.
Mono- and diisopropylated *m*- and *p*-cresols (isothymol derivative).	
N-Oleyl, *N'*-acetyl, *N'*-β-hydroxy-ethylenediamine	
Petrolatum	
Petroleum sulfonate	
Pine oil	
Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b) of this chapter.	For use only at a level not to exceed 0.15 percent by weight of finished fibers.
Polyethylene, oxidized (air blown)	
Polyethylene terephthalate complying in composition with the provisions of § 177.1630(d)(4)(i).	For use only in the manufacture of items for repeated use.
Polyvinyl acetate	
Polyvinyl alcohol	
Potassium soap of a saponified sulfated castor oil	
Sodium bis(2,6-dimethylheptyl-4) sulfosuccinate	
Sodium dioctyl sulfosuccinate	
Sodium dodecyl benzenesulfonate	
Sodium fluoride	For use as preservative only.
Sodium hydrosulfite	
Sodium hypochlorite	
Sodium lauryl sulfate	
Sodium 2-mercaptobenzothiazole	For use as preservative only.
Sodium pentachlorophenate	Do.
Styrene-butadiene copolymer	
Sulfated butyl, isobutyl and propyl oleate	
Tallow	
Tallow, sulfonated	
Titanium dioxide	
Triethanolamine	
Ultramarine blue	
Waxes, petroleum	
Zinc hydrosulfite	

(e) Textile and textile fibers are used as articles or components of articles that contact dry food only.

(f) The provisions of this section are not applicable to jute fibers used as prescribed by § 178.3620(d)(2) of this chapter.

§ 177.2910 Ultra-filtration membranes.

Ultra-filtration membranes identified in paragraph (a) of this section may be safely used in the processing of food, under the following prescribed conditions:

(a) The ultra-filtration membrane

consists of paper impregnated with cured phenol-formaldehyde resin, which is used as a support and is coated with a vinyl chloride-acrylonitrile copolymer.

(b) Any substance employed in the production of ultra-filtration membranes that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with the specifications of such regulation.

(c) Ultra-filtration membranes are used in the physical separation of dissolved or colloidally suspended varying molecular size components of liquids during the commercial processing of bulk quantities of food.

(d) Ultra-filtration membranes shall be maintained in a sanitary manner in accordance with good manufacturing practice so as to prevent potential microbial adulteration of the food.

(e) To assure safe use of the ultra-filtration membranes, the label or labeling shall include adequate directions for a pre-use treatment, consisting of conditioning and washing with a minimum of 8 gallons of potable water prior to their first use in contact with food.

(f) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

(Secs. 201(s), 402, 409, 701(a), 52 Stat. 1046–1047 as amended, 1055, 72 Stat. 1784–1788 (21 U.S.C. 321(s), 342, 348, 371(a)))

PART 178—INDIRECT FOOD ADDITIVES; ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

Subpart A—[Reserved]

Subpart B—Substances Utilized To Control the Growth of Microorganisms

Sec.
178.1010 Sanitizing solutions.

Subpart C—Antioxidants and Stabilizers

178.2010 Antioxidants and/or stabilizers for polymers.
178.2550 4-Hydroxymethyl-2, 6-di-*tert*-butylphenol.
178.2650 Octyltin stabilizers in vinyl chloride plastics.

Subpart D—Certain Adjuvants and Production Aids

178.3010 Adjuvant substances used in the manufacture of foamed polystyrene.
178.3120 Animal glue.
178.3130 Antistatic and/or antifogging agents in food-packaging materials.
178.3280 Castor oil, hydrogenated.
178.3290 Chromic chloride complexes.
178.3300 Corrosion inhibitors used for steel or tinplate.
178.3400 Emulsifiers and/or surface-active agents.
178.3450 Esters of stearic and palmitic acids.
178.3480 Fatty alcohols, synthetic.
178.3500 Glycerin, synthetic.
178.3520 Industrial starch-modified.
178.3530 Isoparaffinic petroleum hydrocarbons, synthetic.
178.3550 Kaolin-modified.
178.3570 Lubricants with incidental food contact.
178.3600 Methyl glucoside-coconut oil ester.
178.3610 α-Methylstyrene-vinyltoluene resins, hydrogenated.
178.3620 Mineral oil.
178.3650 Odorless light petroleum hydrocarbons.
178.3700 Petrolatum.
178.3710 Petroleum wax.
178.3720 Petroleum wax, synthetic.
178.3730 Piperonyl butoxide and pyrethrins as components of bags.
178.3740 Plasticizers in polymeric substances.
178.3750 Polyethylene glycol (mean molecular weight 200–9, 500).
178.3760 Polyethylene glycol (400) monolaurate.
178.3770 Polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids.
178.3780 Polyhydric alcohol esters of long chain monobasic acids.
178.3790 Polymer modifiers in semirigid and rigid vinyl chloride plastics.
178.3800 Preservatives for wood.
178.3850 Reinforced wax.
178.3860 Release agents.
178.3870 Rosins and rosin derivatives.
178.3900 Sodium pentachlorophenate.
178.3910 Surface lubricants used in the manufacture of metallic articles.
178.3930 Terpene resins.
178.3940 Tetraethylene glycol di-(2-ethylhexoate).
178.3950 Tetrahydrofuran.
178.3970 Ultramarine blue.

AUTHORITY: Secs. 409, 701, 52 Stat. 1055–1056 as amended, 72 Stat. 1785–1788 as amended (21 U.S.C. 348, 371), unless otherwise noted.

Subpart A—[Reserved]

Subpart B—Substances Utilized To Control the Growth of Microorganisms

§ 178.1010 Sanitizing solutions.

Sanitizing solutions may be safely used on food-processing equipment and utensils, and on other food-contact articles as specified in this section, within the following prescribed conditions:

(a) Such sanitizing solutions are used, followed by adequate draining, before contact with food.

(b) The solutions consist of one of the following, to which may be added components generally recognized as safe and components which are permitted by prior sanction or approval.

(1) An aqueous solution containing potassium, sodium, or calcium hypochlorite, with or without the bromides of potassium, sodium, or calcium.

(2) An aqueous solution containing dichloroisocyanuric acid, trichloroisocyanuric acid, or the sodium or potassium salts of these acids, with or without the bromides of potassium, sodium, or calcium.

(3) An aqueous solution containing potassium iodide, sodium *p*-toluenesulfonchloroamide, and sodium lauryl sulfate.

(4) An aqueous solution containing iodine, butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol having a cloudpoint of 90°–100° C in 0.5 percent aqueous solution and an average molecular weight of 3,300, and ethylene glycol monobutyl ether. Additionally, the aqueous solution may contain diethylene glycol monoethyl ether as an optional ingredient.

(5) An aqueous solution containing elemental iodine, hydriodic acid, α-(*p*-nonylphenyl) - *omega*-hydroxypoly(oxyethylene) (complying with the identity prescribed in § 178.3400(c) and having a maximum average molecular weight of 748) and/or polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 1,900). Additionally, the aqueous solution may contain isopropyl alcohol as an optional ingredient.

(6) An aqueous solution containing elemental iodine, sodium iodide, sodium dioctylsulfosuccinate, and polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 1,900).

(7) An aqueous solution containing dodecylbenzenesulfonic acid, polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 2,800). In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk.

(8) An aqueous solution containing elemental iodine, butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol having a minimum average molecular weight of 2,400 and α-lauroyl-*omega*-hydroxypoly (oxyethylene) with an average 8–9 moles of ethylene oxide and an average molecular weight of 400. In addition to use on food-processing equipment and utensils, this solution may be used on beverage containers, including milk containers or equipment. Rinse water treated with this solution can be recirculated as a preliminary rinse. It is not to be used as final rinse.

(9) An aqueous solution containing *n*-alkyl (C_{12}–C_{16}) benzyldimethylammonium chloride compounds having average molecular weights of 351–380 and consisting principally of alkyl groups with 12–16 carbon atoms with or without not over 1 percent each of groups with 8 and 10 carbon atoms. Additionally, the aqueous solution may contain isopropyl alcohol as an optional ingredient.

(10) An aqueous solution containing trichloromelamine and either sodium lauryl sulfate or dodecylbenzenesulfonic acid. In addition to use on food-processing equipment and utensils and other food-contact articles, this solution may be used on beverage containers except milk containers or equipment.

(11) An aqueous solution containing equal amounts of *n*-alkyl (C_{12}–C_{16}) benzyl dimethyl ammonium chloride and *n*-alkyl (C_{12}–C_{16}) dimethyl ethylbenzyl ammonium chloride (having an average molecular weight of 384). In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(12) An aqueous solution containing the sodium salt of sulfonated oleic acid, polyoxyethylene-polyoxypropylene block polymers (having an average molecular weight of 2,000 and 27 to 31 moles of polyoxypropylene). In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk. All equipment, utensils, glass bottles, and other glass containers treated with this sanitizing solution shall have a drainage period of 15 minutes prior to use in contact with food.

(13) An aqueous solution containing elemental iodine and alkyl (C_{12}–C_{15}) monoether of mixed (ethylene-propylene) polyalkylene glycol, having a cloud-point of 70°–77°C in 1 percent aqueous solution and an average molecular weight of 807.

(14) An aqueous solution containing iodine, butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol, having a cloud-point of 90°–100°C in 0.5 percent aqueous solution and an average molecular weight of 3,300, and polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 2,000).

(15) An aqueous solution containing lithium hypochlorite.

(16) An aqueous solution containing equal amounts of *n*-alkyl (C_{12}–C_{16}) benzyl dimethyl ammonium chloride and *n*-alkyl (C_{12}–C_{14}) dimethyl ethylbenzyl ammonium chloride (having average molecular weights of 377–384), with the optional adjuvant substances tetrasodium ethylenediaminetetraacetate and/or *alpha*-(*p*-nonylphenol)-*omega*-hydroxypoly(oxyethylene) having an average poly(oxyethylene) content of 11 moles. In addition to use of food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(17) An aqueous solution containing di-*n*-alkyl(C_8–C_{10})dimethyl ammonium chlorides and isopropyl alcohol, having average molecular weights of 332–361. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(18) An aqueous solution containing *n*-alkyl(C_{12}–C_{16}) benzyldimethylammonium chloride, sodium metaborate, *alpha*-terpineol and *alpha*[*p*-(1,1,3,3-tetramethylbutyl) phenyl] - *omega* - hydroxy - poly (oxyethylene) produced with one mole of the phenol and 4 to 14 moles ethylene oxide.

(19) An aqueous solution containing sodium dichloroisocyanurate and tetrasodium ethylenediaminetetraacetate. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(20) An aqueous solution containing *ortho*-phenylphenol, *ortho*-benzyl-*para*-chlorophenol, para-tertiaryamylphenol, sodium - *alpha* - alkyl(C_{12}–C_{18}) - *omega*-hydroxypoly(oxyethylene) sulfate with the poly(oxyethylene) content averaging one mole, potassium salts of coconut oil fatty acids, and isopropyl alcohol or hexylene glycol.

(21) An aqueous solution containing sodium dodecylbenzenesulfonate. In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk.

(c) The solutions identified in paragraph (b) of this section will not exceed the following concentrations:

(1) Solutions identified in paragraph (b)(1) of this section will provide not more than 200 parts per million of available halogen determined as available chlorine.

(2) Solutions identified in paragraph (b)(2) of this section will provide not more than 100 parts per million of available halogen determined as available chlorine.

(3) Solution identified in paragraph (b)(3) of this section will provide not more than 25 parts per million of titratable iodine. The solutions will contain the components potassium iodide, sodium *p*-toluenesulfonchloramide, and sodium lauryl sulfate at a level not in excess of the minimum required to produce their intended functional effect.

(4) Solutions identified in paragraph (b) (4), (5), (6), (8), (13), and (14) of this section will contain iodine to provide not more than 25 parts per million of titratable iodine. The adjuvants used with the iodine will not be in excess of the minimum amounts required to accomplish the intended technical effect.

(5) Solutions identified in paragraph (b)(7) of this section will provide not more than 400 parts per million of dodecylbenzenesulfonic acid and not more than 80 parts per million of polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 2,800).

(6) Solutions identified in paragraph (b)(9) of this section shall provide when ready to use no more than 200 parts per million of the active quaternary compound.

(7) Solutions identified in paragraph (b)(10) of this section shall provide not more than sufficient trichloromelamine to produce 200 parts per million of available chlorine and either sodium lauryl sulfate at a level not in excess of the minimum required to produce its intended functional effect or not more than 400 parts per million of dodecylbenzenesulfonic acid.

(8) Solutions identified in paragraph (b)(11) of this section shall provide, when ready to use, no more than 200 parts per million of active quaternary compound.

(9) The solution identified in paragraph (b)(12) of this section shall provide not more than 200 parts per million of sulfonated oleic acid, sodium salt.

(10) Solutions identified in paragraph (b)(15) of this section will provide not more than 200 parts per million of available chlorine and not more than 30 ppm lithium.

(11) Solutions identified in paragraph (b)(16) of this section shall provide not more than 200 parts per million of active quaternary compound.

(12) Solutions identified in paragraph (b)(17) of this section shall provide, when ready to use, a level of 150 parts per million of the active quaternary compound.

(13) Solution identified in paragraph (b)(18) of this section shall provide not more than 200 parts per million of active quaternary compound and not more than 66 parts per million of *alpha*[*p*-(1,1,3,3-tetramethylbutyl) phenyl] - *omega* - hydroxypoly(oxyethylene).

(14) Solutions identified in paragraph (b)(19) of this section shall provide, when ready to use, a level of 100 parts per million of available chlorine.

(15) Solutions identified in paragraph (b)(20) of this section are for single use applications only and shall provide, when ready to use, a level of 800 parts per million of total active phenols consisting of 400 parts per million *ortho*-phenylphenol, 320 parts per million *ortho*-benzyl-*para*-chlorophenol and 80 parts per million *para*-tertiaryamylphenol.

(16) Solution identified in paragraph (b)(21) of this section shall provide not more than 430 parts per million and not less than 25 parts per million of sodium dodecylbenzenesulfonate.

(d) Sanitizing agents for use in accordance with this section will bear labeling meeting the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act.

Subpart C—Antioxidants and Stabilizers

§ 178.2010 Antioxidants and/or stabilizers for polymers.

The substances listed in paragraph (b) of this section may be safely used as antioxidants and/or stabilizers in polymers used in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

(a) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect.

(b) List of substances:

Substances	*Limitations*
N-*n*-Alkyl-*N'*- (carboxymethyl) -*N,N'*-trimethylenediglycine; the alkyl group is even numbered in the range C_{14}—C_{18} and the nitrogen content is in the range 5.4–5.6 weight percent.	For use only: 1. As component of nonfood articles complying with §§ 175.105 and 177.2600 of this chapter. 2. At levels not to exceed 1.35 percent by weight of natural rubber, butadiene-acrylonitrile, butadiene-acrylonitrile-styrene, and butadiene-styrene polymers that are used in contact with nonalcoholic food at temperatures not to exceed room temperature and that are employed in closure-sealing gaskets complying with § 177.1210 of this chapter or in coatings complying with § 175.300, § 176.170, or § 175.320 of this chapter. The average thickness of such coatings and closure-sealing gaskets shall not exceed 0.004 inch.
p-tert-Amylphenolformaldehyde resins produced when one mole of *p-tert*-amylphenol is made to react under acid conditions with one mole of formaldehyde.	For use only at levels not to exceed 2.1% by weight of polyamide resins that are: 1. Derived from dimerized vegetable oil acids (containing not more than 20% of monomer acids) and ethylenediamine. 2. Used in compliance with regulations in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter.
2,6-Bis(1-methylheptadecyl)-*p*-cresol...	For use only at levels not exceeding 0.3 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4. The average thickness of such polymers in the form in which they contact fatty food or food containing more than 8 percent of alcohol shall not exceed 0.004 inch.

Substances	Limitations
1,3-Butanediol	For use only: 1. As provided in §§ 175.105 and 177.2600 of this chapter. 2. At levels not to exceed 0.5 percent by weight of polystyrene, rubber-modified polystyrene, or olefin polymers complying with § 177.1520 (c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4, or complying with other sections in this Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, used in articles that contact food only under the conditions described in § 176.170 (c) of this chapter, table 2, under conditions of use C through G.
Butylated, styrenated cresols produced when equal moles of isobutylene, styrene, and a metacresol-paracresol mixture having a no more than 3° C distillation range including 202° C are made to react so that the final product meets the following specifications: Not less than 93 pct by weight of total alkylated phenols consisting of 13–25 pct by weight of butylated *m*- and *p*-cresols, 26–38 pct by weight of styrenated *m*- and *p*-cresols, 37–49 pct by weight of butylated styrenated *m*- and *p*-cresols, and not more than 10 pct by weight total of alkylated xylenols, alkylated *o*-cresol, alkylated phenol, and alkylated ethylphenol; acidity not more than 0.003 pct; and refractive index at 25° C of 1.5550–1.5650, as determined by ASTM Method D 1218–61.	
2-*tert*-Butyl-6(3-*tert*-butyl-4-hydroxyphenyl)-*p*-cumenyl bis(*p*-nonylphenyl) phosphite; the nonyl group is a propylene trimer isomer and the phosphorus content is in the range 3.8–4.0 weight percent.	For use only: 1. As components of nonfood articles complying with §§ 175.105 and 177.2600 of this chapter. 2. At levels not to exceed 1.35 percent by weight of natural rubber, butadiene-acrylonitrile, butadiene-acrylonitrile-styrene, and butadiene-styrene polymers that are used in contact with nonalcoholic food at temperatures not to exceed room temperature and that are employed in closure-sealing gaskets complying with § 177.1210 of this chapter or in coatings complying with § 175.300, § 175.320, or § 176.170 of this chapter. The average thickness of such coatings and closure-sealing gaskets shall not exceed 0.004 inch.
2-(3′-*tert*-Butyl-2′-hydroxy-5′-methylphenyl)-5-chlorobenzotriazole with a melting point of 137–141° C.	For use only at levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, provided that the finished polymer contacts foods only of the types identified in categories I, II, IV–B, VI–A and B, VII–B, and VIII in table 1, § 176.170 of this chapter.
4,4′-Butylidenebis(6-*tert*-butyl-*m*-cresol)	For use only. 1. As provided in §§ 175.105 and 177.2600 of this chapter. 2. At levels not to exceed 0.5% by weight of polypropylene complying with § 177.1520 of this chapter and for use at levels not to exceed 0.3% by weight of polyethylene complying with § 177.1520 of this chapter, provided that the finished polypropylene and polyethylene contact food only of the types identified in § 176.170(c) of this chapter, table 1, under categories I, II, VI–B, and VIII.
Calcium benzoate	
Calcium myristate	
Calcium ricinoleate	For use only at levels not to exceed 1 pct by weight of polyoxymethylene copolymer as provided in § 177.2470(b)(1) of this chapter.
Calcium stearate	
Cupric acetate and lithium iodide	For use at levels not exceeding 0.025 pct cupric acetate and 0.065 pct lithium iodide by weight of nylon 66 resins complying with § 177.1500 of this chapter; the finished resins are used or are intended to be used to contain foods during oven baking or oven cooking at temperatures above 250° F. The average thickness of such resins in the form in which they contact food shall not exceed 0.0012 inch.
Cuprous iodide	For use at levels not exceeding 0.01 percent cuprous iodide by weight of nylon 66T resins complying with § 177.1500 of this chapter; the finished resins are used or are intended to be used to contain foods during oven baking or oven cooking at temperatures above 250° F. The average thickness of such resins in the form in which they contact food shall not exceed 0.001 inch.
Cuprous iodide and cuprous bromide	For use at levels not exceeding 0.0025 percent cuprous iodide and 0.0175 percent cuprous bromide by weight of nylon 66 resins complying with § 177.1500 of this chapter; the finished resins are used or are intended to be used to contain foods during oven baking or oven cooking at temperatures above 250° F. The average thickness of such resins in the form in which they contact food shall not exceed 0.0015 inch.
Cyanoguanidine	For use only at levels not to exceed 1 pct by weight of polyoxymethylene copolymer as provided in § 177.2470(b)(1) of this chapter.
Cyclic neopentanetetrayl bis(octadecyl phosphite); the phosphorus content is in the range of 7.8–8.2 weight percent.	For use only: 1. At levels not to exceed 0.25 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 2.1, and 3.1. 2. At levels not to exceed 0.25 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 2.2, that contact food Types I, II, VI–A, VII–B, and VIII described in table 1 of § 176.170(c) of this chapter under conditions of use B (for boil-in-bag applications), C, D, E, F, G, and H described in table 2 of § 176.170(c) of this chapter. 3. At levels not to exceed 0.15 pct by weight of olefin polymers complying with § 177.1520, items 1.1 and 3.2, that contact food Types I, II, VI–A, VII–B, and VIII described in table 1 of § 176.170(c) of this chapter under conditions of use B (for boil-in-bag applications), C, D, E, F, G, and H described in table 2 of § 176.170(c) of this chapter. 4. At levels not to exceed 0.20 percent by weight of polystyrene and/or rubber modified polystyrene complying with § 177.1640 of this chapter that contact food under conditions of use E, F, and G described in table 2 of § 176.170(c) of this chapter.
4,4′-Cyclohexylidenebis(2-cyclohexylphenol).	For use only at levels not to exceed 0.1 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4: *Provided*, That the finished polymers contact food only of the types identified in § 176.170(c) of this chapter, table 1, under categories I, II, IV–B, VI, VII–B, and VIII.
Dicetyl thiodipropionate having a melting point of 59°–62° C. as determined by ASTM Method E–324 and a saponification value in the range 176–183 as determined by ASTM Method D–1962.	The concentration of this additive and any other permitted antioxidants in the finished food-contact article shall not exceed a total of 0.5 milligram per square inch of food-contact surface.
Dimyristyl thiodipropionate having a melting point of 48°–50° C. as determined by ASTM Method E–324 and a saponification equivalent in the range 280–290 as determined by ASTM Method D–1962.	Finished food-contact articles containing this additive shall meet the extractives limitations prescribed in § 176.170(c) of this chapter.

Substances	*Limitations*
N,N'-Diphenylthiourea	For use only: 1. At levels not to exceed 0.5 percent by weight of polyvinyl chloride and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. 2. At levels not to exceed 0.5 pct by weight of vinyl chloride-vinyl acetate copolymers containing not more than 20 molar pct of vinyl acetate.
2,6-Di-*tert*-butyl-4-ethylphenol	For use only in contact with nonalcoholic foods: 1. At levels not exceeding 0.04 mg/in² of food contact surface and not exceeding 0.1 pct by weight in ethylene polymers and copolymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, 3.2, and 3.3; § 177.1350 of this chapter. The average thickness of such polymers and copolymers in the form in which they contact food shall not exceed 0.0025 in. 2. At levels not exceeding 0.04 mg/in² of food contact surface in ethylene polymers and copolymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, 3.2, and 3.3; § 177.1340; and § 177.1350 of this chapter. The average thickness of such polymers and copolymers in the form in which they contact food shall be greater than 0.0025 in but shall not exceed 0.025 in.
Hydrogenated 4,4'-isopropylidenediphenolphosphite ester resins produced by the condensation of 1 mole of triphenyl phosphite and 1.5 moles of hydrogenated 4,4'-isopropylidenediphenol such that the finished resins have a molecular weight in the range of 2,400–3,000, a phosphorous content of 6.5–6.9 percent, and contain no more than 2.2 percent by weight of residual free phenol.	For use only at levels not to exceed 0.55 percent by weight of vinyl chloride copolymers complying with § 177.1980 of this chapter and/or polyvinyl chloride when such vinyl chloride homo-and/or copolymers are used in the manufacture of rigid vinyl chloride plastic bottles intended for contact with edible oils (including edible oil in simple mixture or emulsion form), all types of dressings for salads, and food of types VIII and IX described in table 1 of § 176.170(c) of this chapter. The finished food-contact article containing this stabilizer, when extracted with distilled water at 135° F for 1 week (168 hours), using a volume-to-surface ratio of 5 milliliters per square inch of surface tested, shall yield extracted phenol not to exceed 0.008 milligram per square inch of food-contact surface and shall yield extracted organophosphates (total phosphates minus inorganic phosphates) not to exceed 0.0001 milligram per square inch of food-contact surface.
2-Hydroxy-4-isooctoxy-benzophenone. Chemical Abstracts (CA) name: Methanone, [2-hydroxy-4-(isooctyloxy) phenyl]phenyl; CA Registry No.: 33059-05-1.	For use only at levels not to exceed 0.5 pct by weight of olefin copolymers complying with § 177.1520(c) of this chapter: Items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3 or 4: *Provided*, That the finished polymer contacts food only of the types identified in § 176.170(c) of this chapter, table 1, under categories I, VII–B and VIII under conditions of use E, F, and G described in table 2 of § 176.170(c) of this chapter.
2(2'-Hydroxy-5'-methylphenyl) benzotriazole meeting the following specification: Melting point 126°–132° C.	For use only: 1. As component of nonfood articles complying with § 177.1010 of this chapter. 2. At levels not to exceed 0.25 percent by weight of rigid polyvinyl chloride and/or rigid vinyl chloride copolymers complying with § 177.1980 of this chapter. 3. In polystyrene that complies with § 177.1640 of this chapter and that is limited to use in contact with dry food of type VIII described in table 1 of § 176.170(c) of this chapter. 4. At levels not to exceed 0.25 percent by weight of polystyrene and/or rubber-modified polystyrene polymers complying with § 177.1640 of this chapter intended to contact nonalcoholic food: *Provided*, That the finished basic rubber-modified polystyrene polymers in contact with fatty foods shall contain not less than 90 weight percent of total polymer units derived from styrene monomer.
2-Hydroxy-4-*n*-octoxy-benzophenone	For use only at levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4: *Provided*, That the finished polymer contacts food only of the types identified in § 176.170(c) of this chapter, table 1, under categories I, IV–B, VII–B, and VIII, and under the conditions of use B through H described in table 2 of § 176.170(c) of this chapter.
4,4'-Isopropylidenediphenol alkyl(C_{12}–C_{15}) phosphites; the phosphorus content is in the range of 5.2–5.6 weight percent.	For use only at levels not exceeding 1.0 percent by weight in rigid polyvinyl chloride and/or rigid vinyl chloride copolymers complying with §§ 177.1950, 177.1970 or 177.1980 of this chapter, and used in contact with food, except milk, only under the conditions described in § 176.170(c) of this chapter, table 2, under conditions of use D through G.
Magnesium salicylate	For use only in rigid polyvinyl chloride and/or in rigid vinyl chloride copolymers complying with § 177.1980 of this chapter: *Provided*, That total salicylates (calculated as the acid) do not exceed 0.3 percent by weight of such polymers.
2,2'-Methylenebis (6-*tert*-butyl-4-ethylphenol).	For use only: 1. In acrylonitrile-butadiene-styrene copolymers at levels not to exceed 0.6 percent by weight of the copolymer. 2. In semirigid and rigid acrylic and modified acrylic plastics complying with § 177.1010 of this chapter at levels not to exceed 0.1 pct by weight of the plastic.
4,4'-Methylenebis (2,6-di-*tert*-butylphenol).	For use only: 1. As provided in § 175.105 of this chapter. 2. At levels not to exceed 0.25 percent by weight of petroleum hydrocarbon resins used in compliance with regulations in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter. 3. At levels not to exceed 0.25 pct by weight of terpene resins used in compliance with regulations in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter. 4. At levels not to exceed 0.5 percent by weight of polyethylene complying with § 177.1520 of this chapter: *Provided*, That the polyethylene end product contacts foods only of the types identified in categories I, II, IV–B, VI, VII–B, and VIII in table 1, § 176.170(c) of this chapter. 5. At levels not to exceed 0.5 percent by weight of polybutadiene used in rubber articles complying with § 177.2600 of this chapter: *Provided*, That the rubber end product contacts foods only of the types identified in categories I, II, IV–B, VI, VII–B, and VIII in table 1, § 176.170(c) of this chapter.
2,2'-Methylenebis (4-methyl-6-*tert*-butylphenol).	For use only: 1. At levels not to exceed 0.1 pct by weight of olefin polymers complying with sec. 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4 used in articles that contact food of the types identified in sec. 176.170(c) of this chapter, table 1, under categories I, II, IV–B, VI, VII–B, and VIII. 2. At levels not to exceed 1 pct by weight of polyoxymethylene copolymer as provided in sec. 177.2470(b)(1) of this chapter. 3. At levels not to exceed 0.5 pct by weight of polyoxymethylene homopolymer as provided in § 177.2480(b)(1) of this chapter.

Substances	*Limitations*
2,2'-Methylenebis[6-(1-methylcyclohexyl)-*p*-cresol].	For use only: 1. As provided in § 177.1210 of this chapter. 2. At levels not to exceed 0.2 pct by weight of polyethylene complying with § 177.1520 of this chapter: *Provided*, That the finished polyethylene contacts foods only of the type identified in § 176.170(c) of this chapter, table 1, under categories I, II, VI–B, and VIII. 3. In polyethylene complying with § 177.1520 of this chapter: *Provided*, That the finished polyethylene contacts foods only of the types identified in § 176.170(c) of this chapter, table 1, under categories III, IV, V, VI–A, VII, and IX, and only at temperatures not to exceed room temperature: *And further provided*, That percentage concentration of the antioxidant in the polyethylene, when multiplied by the thickness in inches of the finished polyethylene, shall not be greater than 0.0005.
2,2'-Methylenebis(4-methyl-6-nonylphenol) and 2,6-bis(2-hydroxy-3-nonyl-5-methyl-benzyl)-*p*-cresol mixtures (varying proportions).	For use only in acrylonitrile-butadiene-styrene copolymers used in contact with nonalcoholic foods.
Nylon 66/610/6 terpolymer. (see § 177.1500 of this chapter for identification).	For use only at levels not to exceed 1.5 percent by weight of polyoxymethylene homopolymer as provided in § 177.2480(b)(1) of this chapter.
Octadecyl 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate.	For use only. 1. At levels not exceeding 0.25 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4. When such polymers are used in contact with fatty food, the percentage concentration of the antioxidant and/or stabilizer multiplied by the thickness in inches of the finished olefin polymer shall not exceed a factor of 0.0025, except that concentrations of 0.05 percent or less may be used without limitation on thickness. 2. As provided in §§ 175.105 and 177.1010(a)(5) of this chapter. 3. At levels not exceeding 0.25 percent by weight of polystyrene and or rubber-modified polystyrene polymers complying with § 177.1640 of this chapter, except that the finished basic rubber-modified polystyrene polymers in contact with fatty foods shall contain not less than 85 weight percent of total polymer units derived from styrene monomer. 4. At levels not to exceed 0.5 percent by weight of acrylonitrile-butadiene-styrene copolymers used in accordance with prior sanction or regulations in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter. 5. At levels not exceeding 0.25 percent by weight of olefin copolymers complying with 177.1520(c) of this chapter, items 3.4 and 3.5: *Provided*, That the finished polymer contacts nonfatty foods only of the types identified in § 176.170(c) of this chapter, table 1, under categories I, II, IV–B, VI, VII–B, and VIII.
Pentaerythritol and its stearate ester....	For use only in rigid polyvinyl chloride and/or in rigid vinyl chloride copolymers complying with § 177.1980 of this chapter: *Provided*, That the total amount of pentaerythritol and/or pentaerythritol stearate (calculated as free pentaerythritol) does not exceed 0.4 percent by weight of such polymers.
Poly(1,4 - cyclohexylenedimethylene - 3,3'-thiodipropionate) partially terminated with stearyl alcohol and produced when approximately equal moles of 1,4-cyclohexanedimethanol and 3,3'-thiodipropionic acid are made to react in the presence of stearyl alcohol so that the final product has an average molecular weight in the range of 1,800–2,200, as determined by vapor pressure osmometry, and has a maximum acid value of 2.5.	For use only: 1. In polypropylene complying with § 177.1520(c) of this chapter, item 1.1, and used in contact with nonfatty, nonalcoholic food. 2. At levels not to exceed 0.5 percent by weight of polypropylene complying with § 177.1520(c) of this chapter, item 1.1, and used in contact with fatty, nonalcoholic food. The average thickness of such polymers in the form in which they contact fatty nonalcoholic food shall not exceed 0.005 inch.
Poly[(1,3 - dibutyldistannthianedityldene) - 1,3-dithio] having the formula $[C_4H_9Sn_2S_4]_n$ (where *n* averages 1.5–2) and produced so as to meet the following specifications: Softening point, 130–145° C; volatile components at 150° C, less than 1.0 percent; sulphur (sulfide) content in the range 20.5–22.0 percent; tin content in the range 52.0–53.2 percent.	For use only at levels not to exceed 0.2 pct by weight in polyvinyl chloride resin where such resin constitutes not less than 98.7 pct of a finished semirigid or rigid polyvinyl chloride food-contact surface, provided that the finished food-contact article is employed only to package meat, cheese, and food types I, VIII, and IX as described in table 1 of § 176.170(c) of this chapter. The finished food-contact article containing this stabilizer, when extracted with refined cottonseed oil at 120° F. for 48 hours, using a volume-to-surface ratio of 2 milliliters per square inch of surface tested, shall yield tin (Sn) not to exceed 0.0005 milligram per square inch of food-contact surface.
Potassium bromide and either cupric acetate or cupric carbonate.	For use at levels not exceeding 0.18 pct potassium bromide and 0.005 pct copper as cupric acetate or cupric carbonate by weight of nylon 66 resins complying with § 177.1500 of this chapter; the finished resins are used or are intended to be used to contain foods during oven baking or oven cooking at temperatures above 250° F. The average thickness of such resins in the form in which they contact food shall not exceed 0.0015 inch.
Tetrakis[methylene (3,5 - di-*tert*-butyl-4-hydroxyhydrocinnamate)] methane.	For use only: 1. At levels not to exceed 0.5 pct by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4. 2. At levels not to exceed 0.05 pct by weight of ethylene-methacrylic acid copolymers complying with § 177.1330 of this chapter and ethylene-acrylic acid copolymers complying with § 177.1310 of this chapter. The average thickness of such copolymers in the form in which they contact food shall not exceed 0.005 inch. 3. At levels not to exceed 0.5 pct by weight of the following polymers when used in articles that contact nonalcoholic food: polystyrene and rubber-modified polystyrene complying with § 177.1640 of this chapter; ethylene-acrylic acid copolymers complying with § 177.1310 of this chapter; ethylene-vinyl acetate copolymers complying with § 177.1350 of this chapter; ethylene-methacrylic acid copolymers, ethylene-methacrylic acid-vinyl acetate copolymers and their partial salts complying with § 177.1330 of this chapter; isobutylene polymers complying with § 177.1420 of this chapter; and styrene butadiene copolymers used in compliance with regulations in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter. 4. At levels not to exceed 1 pct by weight of polyoxymethylene copolymer as provided in sec. 177.2470(b)(1) of this chapter. 5. At levels not to exceed 0.5 pct by weight of polyoxymethylene homopolymer as provided in § 177.2480(b)(1) of this chapter.
4,4-Thiobis(6-*tert*-butyl-*m*-cresol).....	For use only: 1. As provided in §§ 175.105 and 177.2600 of this chapter. 2. At levels not to exceed 0.25% by weight of polyethylene complying with § 177.1520 of this chapter: *Provided*, That the specific gravity of the polyethylene is not less than 0.926: *And further provided*, That the finished polyethylene contacts food only of the types identified in § 176.170(c) of this chapter, table 1, under categories I, II, VI–B, and VIII.

Substances	*Limitations*
Thiodipropionic acid	For use only: 1. At levels not to exceed 0.5 pct by weight of polymers except nylon resins identified in § 177.1500 of this chapter. 2. At levels not to exceed 1 pct by weight of nylon resins identified in § 177.1500 of this chapter.
1,3,5-Trimethyl-2,4,6-tris(3,5-di-*tert*-butyl-4-hydroxybenzyl)benzene.	
Tri(mixed mono- and dinonylphenyl) phosphite (which may contain not more than 1% by weight of triisopropanolamine).	
1,3,5-Tris(3,5-di-*tert*-butyl-4-hydroxybenzyl)-*s*-triazine-2,4,6(1*H*,3*H*,5*H*)trione.	For use only: 1. At levels not to exceed 0.25 pct by weight of polypropylene complying with § 177.1520 of this chapter. 2. In polyethylene complying with § 177.1520 of this chapter: (a) At levels not to exceed 0.1 weight pct. (b) At levels not to exceed 0.5 weight pct in contact with nonfatty food. 3. At levels not to exceed 0.5 pct by weight of ethylene-propylene-5-ethylidine-2-norbornene terpolymers complying with §177.1520 of this chapter. The maximum thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch.
1,3,5-Tris(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamoyl)hexahydro-*s*-triazine.	For use only in contact with nonfatty foods: 1. At levels not to exceed 0.25 percent by weight of polypropylene complying with § 177.1520 of this chapter. 2. At levels not to exceed 0.1 percent by weight of polyethylene complying with § 177.1520 of this chapter. 3. At levels not to exceed 0.5 percent by weight of ethylene-propylene-5-ethylidine-2-norbornene terpolymers complying with § 177.1520 of this chapter. The maximum thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch.
Tris(2-methyl-4-hydroxy-5-*tert*-butylphenyl) butane.	For use only: 1. At levels not to exceed 0.25 percent by weight of polymers used as provided in § 176.180 of this chapter. 2. At levels not to exceed 0.25 percent by weight of the following polymers when used in articles that contact food of types I, II, IV–B, VI–B, VII–B, and VIII described in table 1 of § 176.170(c) of this chapter: Olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4 or complying with other sections in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter; vinyl chloride polymers; and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. 3. At levels not to exceed 0.1 percent by weight of the following polymers when used in articles that contact food of types III, IV–A, V, VI–A, VI–C, VII–A, and IX described in table 1 of § 176.170(c) of this chapter: Olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4 or complying with other sections in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter; vinyl chloride polymers; and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. 4. As provided in § 175.105 of this chapter. 5. At levels not to exceed 0.2 percent by weight of polystyrene and/or modified polystyrene polymers identified in § 177.1640 of this chapter. 6. At levels not to exceed 0.25 percent by weight of acrylonitrile-butadiene-styrene copolymers used in contact with nonalcoholic foods.
Zinc dibutyldithiocarbamate	For use only at levels not to exceed 0.2 percent by weight of isobutylene-isoprene copolymers complying with § 177.1420 of this chapter: *Provided*, That the finished copolymers contact food only of the types identified in § 176.170(c) of this chapter, table 1, under types V, VII, VIII, and IX.
Zinc palmitate Zinc salicylate	For use only in rigid polyvinyl chloride and/or in rigid vinyl chloride copolymers complying with § 177.1980 of this chapter: *Provided*, That total salicylates (calculated as the acid) do not exceed 0.3 percent by weight of such polymers.
Zinc stearate	

§ 178.2550 4-Hydroxymethyl-2,6-di-*tert*-butylphenol.

4-Hydroxymethyl-2,6-di-*tert*-butylphenol may be safely used as an antioxidant in articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) The additive has a solidification point of 140°–141° C.

(b) The concentration of the additive and any other permitted antioxidants in the finished food-contact article does not exceed a total of 0.5 milligram per square inch of food-contact surface.

§ 178.2650 Octyltin stabilizers in vinyl chloride plastics.

The octyltin chemicals identified in paragraph (a) of this section may be safely used alone or in combination, at levels not to exceed a total of 3 parts per hundred of resin, as stabilizers in polyvinyl chloride and vinyl chloride copolymers complying with the provisions of § 177.1950 or § 177.1980 of this chapter and that are intended for use in contact with food of types I, II, III, IV (except liquid milk), V, VI (except malt beverages and carbonated nonalcoholic beverages), VII, VIII, and IX described in table 1 of § 176.170(c) of this chapter, in accordance with the following prescribed conditions:

(a) For the purpose of this section, the octyltin chemicals are those identified in paragraphs (a) (1) and (2) of this section.

(1) Di(*n*-octyl)tin S,S'-bis(isooctylmercaptoacetate) is an octyltin chemical having 15.1 to 16.4 percent by weight of tin (Sn) and having 8.1 to 8.9 percent by weight of mercapto sulfur. It is made from (di(*n*-octyl)tin dichloride or di(*n*-octyl)tin oxide. The isooctyl radical in the mercaptoacetate is derived from oxo process isooctyl alcohol. Di(*n*-octyl)tin dichloride has an organotin composition that is not less than 95 percent by weight di(*n*-octyl)tin dichloride, not more than 5 percent by weight total of *n*-octyltin trichloride and/or tri(*n*-octyl)tin chloride and/or higher (more than eight (8) carbon) alkyl tin chlorides, not more than 0.2 percent by weight total of other eight (8) carbon isomeric alkyltin derivatives, and not more than 0.1 percent by weight lower (less than eight (8) carbon) homologous alkyltin derivatives. Di(*n*-octyl)tin oxide has an organotin composition that is not less than 95 percent by weight di(*n*-octyl) tin oxide, not more than 5 percent by weight of bis [tri(*n*-octyl)tin] oxide, and/or mono *n*-octyltin oxide, and/or higher (more than eight (8) carbon) alkyltin oxides, not more than 0.2 percent by weight of isomeric-octyltin oxides, and not more than 0.1 percent by weight of lower (less than eight (8) carbon) alkyltin oxides.

(2) Di(*n*-octyl)tin maleate polymer is an octyltin chemical having the formula $[(C_8H_{17})_2SnC_4H_2O_4]_n$ (where n is between 2 and 4 inclusive), having 25.2 to 26.6 percent by weight of tin (Sn) and having a saponification number of 225 to 255. It is made from di(*n*-octyl)tin dichloride or di(*n*-octyl)tin oxide meeting the specifications prescribed for di(*n*-octyl)tin dichloride or di(*n*-octyl)tin oxide in paragraph (a)(1) of this section.

(b) The vinyl chloride plastic containers, film or panels in the finished form in which they are to contact food, shall meet the following limitations:

(1) The finished plastics intended for contact with foods of the types listed in this section shall be extracted with the solvent or solvents characterizing those types of foods as determined from table 2 of § 176.170(c) of this chapter at the temperature reflecting the conditions of intended use as determined therein. Additionally, extraction tests for acidic foods shall be included and simulated by 3-percent acetic acid at temperatures specified for water in table 2 of § 176.170(c) of this chapter. The extraction tests shall cover at least three equilibrium periodic determinations, as follows:

(i) The exposure time for the first determination shall be at least 72 hours for aqueous solvents, and at least 6 hours for heptane.

(ii) Subsequent determinations shall be at a minimum of 24-hour intervals for aqueous solvents, and 2-hour intervals for heptane. These tests shall yield di(*n*-octyl)tin *S,S'*-bis(isooctylmercaptoacetate) or di(*n*-octyl)tin maleate polymer or any combination thereof not to exceed 0.5 part per million as determined by an analytical method available upon request from the Commissioner of Food and Drugs.

(2) In lieu of the tests prescribed in paragraph (b)(1) of this section, the finished plastics intended for contact with foods only of types II, V, VI–A (except malt beverages), and VI–C may be end-tested with food-simulating solvents, under conditions of time and temperature, as specified below, whereby such tests shall yield the octyltin residues cited in paragraph (b)(1) of this section not in excess of 0.5 ppm:

	Food-simulating solvent	Time (hours)	Temperature (degrees Fahrenheit)
Type II	Acetic acid, 3 pct	48	135
Type V	Heptane	2	100
Type VI-A	Ethyl alcohol, 8 pct.	24	120
Type VI-C	Ethyl alcohol, 50 pct.	24	120

Subpart D—Certain Adjuvants and Production Aids

§ 178.3010 Adjuvant substances used in the manufacture of foamed polystyrene.

The following substances may be safely used as adjuvants in the manufacture of foamed polystyrene intended for use in contact with food, subject to any prescribed limitations:

List of substances	*Limitations*
Isopentane	For use as blowing agent.
n-Pentane	Do.
1,1,2,2-Tetrachloroethylene	For use only as a blowing agent adjuvant at a level not to exceed 0.3% by weight of finished foamed polystyrene intended for use in contact with food only of the types identified in § 176.170(c) of this chapter, table 1, under categories I, II, VI, and VIII.
Toluene	For use only as a blowing agent adjuvant at a level not to exceed 0.35% by weight of finished foamed polystyrene.

§ 178.3120 Animal glue.

Animal glue may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) Animal glue consists of the proteinaceous extractives obtained from hides, bones, and other collagen-rich substances of animal origin (excluding diseased or rotted animals), to which may be added other optional adjuvant substances required in its production or added to impart desired properties.

(b) The quantity of any substance employed in the production of animal glue does not exceed the amount reasonably required to accomplish the intended physical or technical effect nor any limitation further provided.

(c) Any substance employed in the production of animal glue and which is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

(d) Optional adjuvant substances employed in the production of animal glue include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in animal glue and used in accordance with such sanction or approval.

(3) Substances identified in this paragraph (d) (3) and subject to such limitations as are provided:

List of substances	*Limitations*
Alum (double sulfate of aluminum and ammonium, potassium, or sodium).	
4-Chloro-3-methylphenol(*p*-chlorometacresol).	For use as preservative only.
Chromium potassium sulfate (chrome alum).	For use only in glue used as a colloidal flocculant added to the pulp suspension prior to the sheet-forming operation in the manufacture of paper and paper board.
3,5-Dimethyl-1,3,5,2*H*-tetrahydrothiadiazine-2-thione.	For use as preservative only.
Disodium cyanodithioimidocarbonate	Do.
Defoaming agents	As provided in § 176.210 of this chapter.
Ethanolamine	
Ethylenediamine	
Formaldehyde	For use as a preservative only.
Potassium *N*-methyldithiocarbamate	Do.
Potassium pentachlorophenate	Do.
Rosins and rosin derivatives	As provided in § 178.3870.
Sodium chlorate	
Sodium dodecylbenzenesulfonate	
Sodium 2-mercaptobenzothiazole	For use as preservative only.
Sodium pentachlorophenate	Do.
Sodium *o*-phenylphenate	Do.
Zinc dimethyldithiocarbamate	Do.
Zinc 2-mercaptobenzothiazole	Do.

(e) The conditions of use are as follows:

(1) The use of animal glue in any substance or article that is the subject of a regulation in this subpart conforms with any specifications or limitations prescribed by such regulation for the finished form of the substance or article.

(2) It is used as an adhesive or component of an adhesive in accordance with the provisions of § 175.105 of this chapter.

(3) It is used as a colloidal flocculant added to the pulp suspension prior to the sheet-forming operation in the manufacture of paper and paperboard.

(4) It is used as a protective colloid in resinous and polymeric emulsion coatings.

§ 178.3130 Antistatic and/or antifogging agents in food-packaging materials.

The substances listed in paragraph (b) of this section may be safely used as antistatic and/or antifogging agents in food-packaging materials, subject to the provisions of this section:

(a) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect.

(b) List of substances:

List of substances	Limitations
Alpha-(Carboxymethyl)-omega-(tetradecyloxy) poly-oxyethylene)	For use only as an antistatic and/or antifogging agent at levels not to exceed 0.2 pct by weight in polyolefin film not exceeding 0.001 inch thickness.
N-Acyl sarcosines where the acyl group is lauroyl, oleoyl, or derived from the combined fatty acids of coconut oil.	For use only: 1. As antistatic and/or antifogging agent at levels not to exceed a total of 0.15 pct by weight of polyolefin film used for packaging meat, fresh fruits, and fresh vegetables. The average thickness of such polyolefin film shall not exceed 0.003 inch. 2. As antistatic and/or antifogging agent at levels not to exceed a total of 0.15 pct by weight of ethylene-vinyl acetate copolymer film complying with § 177.1350 of this chapter and used for packaging meat, fresh fruits, fresh vegetables, and dry food of type VIII described in table 1 of § 176.170(c) of this chapter. The average thickness of such ethylene-vinyl acetate copolymer film shall not exceed 0.003 inch when used for packaging meat, fresh fruits, and fresh vegetables.
N,N-Bis(2-hydroxyethyl)alkyl(C_{11}-C_{15})amine	For use only as an antistatic agent at levels not to exceed 0.1 pct by weight of polyolefin food-contact films.
N,N-Bis(2-hydroxyethyl) alkylamine, where the alkyl groups (C_{14}-C_{18}) are derived from tallow.	For use only: 1. As an antistatic agent at levels not to exceed 0.15 pct by weight in molded or extruded polyethylene containers that contact food only of the types identified in § 176.170(c) of this chapter, table 1, under types I, IV–B, VI–B, VII–B, and VIII, under the conditions of use E through G described in table 2 of § 176.170(c) of this chapter provided such foods have a pH above 5.0. 2. As an antistatic agent at levels not to exceed 0.10 mg. per square inch of food-contact surface in vinylidene chloride copolymer coatings complying with §§ 175.320, 177.1200, or 177.1630 of this chapter, provided that such coatings contact food only of the types identified in § 176.170(c) of this chapter, table 1, under types I, IV, VII, VIII, and IX under the conditions of use E through G described in table 2 of § 176.170(c) of this chapter. The finished copolymers shall contain at least 70 weight pct of polymer units derived from vinylidene chloride; and shall contain not more than 5 weight pct of total polymer units derived from acrylamide, acrylic acid, fumaric acid, itaconic acid, methacrylic acid, octadecyl methacrylate, and vinyl sulfonic acid.
N,N - Bis(2 - hydroxyethyl) dodecanamide produced when diethanolamine is made to react with methyl laurate such that the finished product: Has a minimum melting point of 36° C; has a minimum amide assay of 90 percent; contains no more than 2 percent by weight of free diethanolamine; and contains no more than 0.5 percent by weight of *N,N'*-bis(2-hydroxyethyl)piperazine, as determined by paper chromatography method.	For use only as an antistatic agent at levels not to exceed 0.5 percent by weight of molded or extruded polyethylene containers intended for contact with honey, chocolate syrup, liquid sweeteners, condiments, flavor extracts and liquid flavor concentrates, grated cheese, light and heavy cream, yogurt, and foods of type VIII as described in table 1 of § 176.170(c) of this chapter.
α-n-Dodecanol-*omega*-hydroxypoly (oxyethylene) produced by the condensation of 1 mole of *n*-dodecanol with an average of 9.5 moles of ethylene oxide to form a condensate having a hydroxyl content of 2.7 to 2.9 pct and having a cloud point of 80° C to 92° C in 1 pct by weight aqueous solution.	For use only as an antistatic agent at levels not to exceed 0.2 pct by weight in low-density polyethylene film having an average thickness not exceeding 0.005 inch.
Glycerol ester mixtures of ricinoleic acid, containing not more than 50 pct monoricinoleate, 45 pct diricinoleate, 10 pct triricinoleate, and 3.3 pct free glycerine.	As an antifogging agent at levels not exceeding 1.5 pct by weight of permitted plasticized vinyl chloride homo-and/or copolymers.

§ 178.3280 Castor oil, hydrogenated.

Hydrogenated castor oil may be safely used in the manufacture of articles or components of articles intended for use in contact with food subject to the provisions of this section.

(a) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect.

(b) The additive is used as follows:

Use	Limitations
1. As a lubricant for vinyl chloride polymers used in the manufacture of articles or components of articles authorized for food-contact use.	For use only at levels not to exceed 4 pct by weight of vinyl chloride polymers.
2. As a component of cellophane	Complying with § 177.1200 of this chapter.
3. As a component of resinous and polymeric coatings.	Complying with § 175.300 of this chapter.
4. As a component of paper and paperboard in contact with aqueous and fatty food.	Complying with § 176.170 of this chapter.
5. As a component of closures with sealing gaskets for food containers.	Complying with § 177.1210 of this chapter.
6. As a component of cross-linked polyester resins.	Complying with § 177.2420 of this chapter.

§ 178.3290 Chromic chloride complexes.

Myristo chromic chloride complex and stearato chronic chloride complex may be safely used as release agents in the closure area of packaging containers intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

(a) The quantity used shall not exceed that reasonably required to accomplish the intended technical effect nor exceed 7 micrograms of chromium per square inch of closure area.

(b) The packaging container which has its closure area treated with the release agent shall have a capacity of not less than 120 grams of food per square inch of such treated closure area.

§ 178.3300 Corrosion inhibitors used for steel or tinplate.

Corrosion inhibitors may be safely used for steel or tinplate intended for use in, or to be fabricated as, food containers or food-processing or handling equipment, subject to the provisions of this section.

(a) The corrosion inhibitors are prepared from substances identified in this section and used subject to the limitations prescribed.

(b) The following corrosion inhibitors or adjuvants are used in amounts not to exceed those reasonably required to accomplish the intended physical or technical effect:

(1) Corrosion inhibitors (active ingredients) used in packaging materials for the packaging of steel or tinplate or articles fabricated therefrom:

List of substances	Limitations
Dicyclohexylamine and its salts of fatty acids derived from animal or vegetable oil.	
Dicyclohexylamine nitrite	
Morpholine and its salts of fatty acids derived from animal or vegetable oils.	

(2) Adjuvants employed in the application and use of corrosion inhibitors:

List of substances	Limitations
Propylene glycol	

§ 178.3400 Emulsifiers and/or surface-active agents.

The substances listed in paragraph (c) of this section may be safely used as emulsifiers and/or surface-active agents in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect; and the quantity that may become a component of food as a result of such use shall not be intended to, nor in fact, accomplish any physical or technical effect in the food itself.

(b) The use as an emulsifier and/or surface-active agent in any substance or article that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specifications and limitations prescribed by such regulation for the finished form of the substance or article.

(c) List of substances:

List of substances	Limitations
α-Alkyl-, α-alkenyl-, and α-alkylaryl-*omega*-hydroxypoly(oxyethylene) mixture consisting of 30 weight pct of α-(2,4,6-triisobutylphenyl)-*omega*-hydroxypoly(oxyethylene) having an average poly(oxyethylene) content of 7 moles and 70 weight pct of a 1:1 weight ratio mixture of α-(Z)-9-octadecenyl-*omega*-hydroxypoly(oxyethylene) having an average poly(oxyethylene) content of 18 moles and α-alkyl(C_{16}–C_{18})-*omega*-hydroxypoly(oxyethylene) having an average poly(oxyethylene) content of 18 moles.	For use only at levels not to exceed 0.5 pct by weight of coatings complying with § 175.320 of this chapter and limited to use as an emulsifier for polyhydric alcohol diesters used as provided in § 178.3770(b). The weight of the finished coating shall not exceed 2 milligrams per square inch of food-contact surface.
α-Alkyl-*omega*-hydroxypoly(oxyethylene) produced by condensation of 1 mole of C_{11}–C_{15} straight-chain randomly substituted secondary alcohols with an average of 7–20 moles of ethylene oxide.	
α-Alkylsulfonate (alkyl group is in the range C_{10}–C_{18} with not less than 50 pct (C_{14}–C_{16}).	For use only: 1. As provided in § 176.170 of this chapter. 2. At levels not to exceed 2 pct by weight of polyvinyl chloride and/or vinyl chloride copolymers complying with § 177.1980 of this chapter.
Ammonium salt of epoxidized oleic acid, produced from epoxidized oleic acid (predominantly dihydroxystearic and acetoxyhydroxystearic acids) meeting the following specifications: Acid number 160–180, saponification number 210–235, iodine number 2–15, and epoxy groups 0–0.4 percent.	For use only: 1. As a polymerization emulsifier at levels not to exceed 1.5 pct by weight of vinyl chloride polymers used as components of nonfood articles complying with §§ 175.105, 175.300, 176.170, 176.180, and 177.1210 of this chapter. Such vinyl chloride polymers are limited to polyvinyl chloride and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. 2. As a polymerization emulsifier at levels not to exceed 1.5 pct by weight of vinyl chloride/vinyl acetate copolymers used as components of nonfood articles complying with §§ 175.105, 175.300, 176.170, 176.180, and 177.1210 of this chapter.
α-Di-*sec*-butylphenyl-*omega*-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of di-*sec*-butylphenol with an average of 4–14 or 30–50 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range 4–14 or 30–50; *sec*-butyl groups are predominantly (90 percent or more) *o*-, *p*-substituents.	
α-Dodecyl-*omega*-hydroxpoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 103–111 and that are produced by the esterification of the condensation product of 1 mole of *n*-dodecyl alcohol with 4–4.5 moles of ethylene oxide.	
α-(*p*-Dodecylphenyl)-*omega*-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of dodecylphenol (dodecyl group is a propylene tetramer isomer) with an average of 4–14 or 30–50 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range 4–14 or 30–50.	
α-(*p*-Nonylphenyl)-*omega*-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 49–59 and that are produced by the esterification of α-(*p*-nonylphenyl)-*omega*-hydroxypoly(oxyethylene) complying with the identity prescribed in § 178.3400(c) and having an average poly(oxyethylene) content of 5.5–6.5 moles.	
α-(*p*-Nonylphenyl)-*omega*-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 62–72 and that are produced by the esterification of α-(*p*-nonylphenyl)-*omega*-hydroxypoly(oxyethylene) complying with the identity prescribed in § 178.3400(c) and having an average poly(oxyethylene) content of 9–10 moles.	
α-(*p*-Nonylphenyl)-*omega*-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 98–110 and that are produced by the esterification of α-(*p*-nonylphenyl)-*omega*-hydroxypoly(oxyethylene) complying with the identity prescribed in § 178.3400(c) and having an average poly(oxyethylene) content of 45–55 moles.	
α-(*p*-Nonylphenyl)-*omega*-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of nonylphenol (nonyl group is a propylene trimer isomer) with an average of 4–14 or 30–50 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted	

List of Substances	Limitations
to produce any product that is a component of the blend shall be in the range 4–14 or 30–50.	
α-(*p*-Nonylphenyl)-*omega*-hydroxypoly (oxyethylene) sulfate, ammonium or sodium salt; the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content average 4 moles.	
Poly(oxypropylene) (45–48 moles) block polymer with poly(oxyethylene). The finished block polymers meet the following specifications: Average molecular weight 11,000–18,000; hydroxyl number 6.2–10.2; cloud point above 100° C. for 10 pct solution.	For use only as a surface-active agent at levels not to exceed 0.5 percent by weight of polyolefin film or polyolefin coatings. Such polyolefin film and polyolefin coatings shall have an average thickness not to exceed 0.005 inch and shall be limited to use in contact with foods that have a pH above 5.0 and that contain no more than 8 pct of alcohol.
Polysorbate 20 (polyoxyethylene (20) sorbitan monolaurate) meeting the following specifications: Saponification number 40–50, acid number 0–2, hydroxyl number 60–108, oxyethylene content 70–74 pct.	
Polysorbate 40 (polyoxyethylene (20) sorbitan monopalmitate) meeting the following specifications: Saponification number 41–52, oxyethylene content 66–70.5 pct.	
Polysorbate 60 conforming to the identity prescribed in § 172.836 of this chapter.	
Polysorbate 65 conforming to the identity prescribed in § 172.838 of this chapter.	
Polysorbate 80 conforming to the identity prescribed in § 172.840 of this chapter.	
Polysorbate 85 (polyoxyethylene (20) sorbitan trioleate) meeting the following specifications: Saponification number 80–95, oxyethylene content 46–50 percent.	
Sodium α-alkylbenzenesulfonate (alkyl group predominantly C_{12} and C_{13} and not less than 95 percent C_{10} to C_{14}).	For use only as a component of nonfood articles complying with §§ 175.300, 175.320, 175.380, 176.170, 176.180, 177.1010, 177.1200, 177.1630, 177.2600, 177.2800, of this chapter and § 178.3120.
Sodium 1,4-dicyclohexyl sulfosuccinate.	
Sodium 1,4-dihexyl sulfosuccinate	
Sodium 1,4-diisobutyl sulfosuccinate	
Sodium dioctyl sulfosuccinate	
Sodium 1,4-dipentyl sulfosuccinate	
Sodium 1,4-ditridecyl sulfosuccinate	
Sodium lauryl sulfate	
Sodium monoalkylphenoxybenzenedisulfonate and sodium dialkylphenoxybenzenedisulfonate mixtures containing not less than 70 pct of the monoalkylated product where the alkyl group is C_8–C_{12}.	
Sorbitan monolaurate meeting the following specifications: Saponification number 153–170; and hydroxyl number 330–360.	
Sorbitan monooleate meeting the following specifications: Saponification number 145–160, hydroxyl number 193–210.	
Sorbitan monopalmitate meeting the following specifications: Saponification No. 140–150; and hydroxyl No. 275–305.	
Sorbitan monostearate conforming to the identity prescribed in § 172.842 of this chapter.	
Sorbitan trioleate meeting the following specifications: Saponification No. 170–190; and hydroxyl No. 55–60.	
Sorbitan tristearate meeting the following specifications: Saponification No. 176–188; and hydroxyl No. 66–80.	
α-[*p*-(1,1,3,3-Tetramethylbutyl)phenyl]-*omega*-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p*-(1,1,3,3-tetramethylbutyl) phenol with an average of 4–14 or 30–40 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range 4–14 or 30–50.	
Tetrasodium *N*-(1,2-dicarboxyethyl)-*N*-octadecyl-sulfosuccinamate.	For use only as a polymerization emulsifier for resins applied to tea-bag material.
α - Tridecyl - *omega* - hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 75–85 and that are produced by the esterification of the condensation product of one mole of "oxo" process tridecyl alcohol with 5.5–6.5 moles of ethylene oxide.	
α - Tridecyl - *omega* - hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 58–70 and that are produced by the esterification of the condensation product of one mole of "oxo" process tridecyl alcohol with 9–10 moles of ethylene oxide.	

(d) The provisions of this section are not applicable to emulsifiers and/or surface-active agents listed in § 175.105(c)(5) of this chapter and used in food-packaging adhesives complying with § 175.105 of this chapter.

§ 178.3450 Esters of stearic and palmitic acids.

The ester stearyl palmitate or palmityl stearate or mixtures thereof may be safely used as adjuvants in food-packaging materials when used in accordance with the following prescribed conditions:

(a) They are used or intended for use as plasticizers or lubricants in polystyrene intended for use in contact with food.

(b) They are added to the formulated polymer prior to extrusion.

(c) The quantity used shall not exceed that required to accomplish the intended technical effect.

§ 178.3480 Fatty alcohols, synthetic.

Synthetic fatty alcohols may be safely used as components of articles intended for use in contact with food, and in synthesizing food additives and other substances permitted for use as components of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) The food additive consists of fatty alcohols meeting the specifications and definition prescribed in § 172.864 of this chapter, except as provided in paragraph (c) of this section.

(b) It is used or intended for use as follows:

(1) As substitutes for the corresponding naturally derived fatty alcohols permitted for use as components of articles intended for use in contact with food by existing regulations in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter: *Provided*, That the use is in compliance with any prescribed limitations.

(2) As substitutes for the corresponding naturally derived fatty alcohols used as intermediates in the synthesis of food additives and other substances permitted for use as components of food-contact articles.

(c) Synthetic fatty alcohols identified in paragraph (c)(1) of this section may contain not more than 0.8 weight percent of total diols as determined by a method available upon request from the Commissioner of Food and Drugs, when used as prescribed in paragraph (c)(2) of this section.

(1) *Synthetic fatty alcohols.* (i) Hexyl, octyl, decyl, lauryl, myristyl, cetyl, and stearyl alcohols meeting the specifications and definition prescribed in § 172.864 of this chapter, except that they may contain not more than 0.8 weight percent total diols.

(ii) Lauryl, myristyl, cetyl, and stearyl alcohols manufactured by the process described in § 172.864(a)(2) of this chapter such that lauryl and myristyl alcohols meet the specifications in § 172.864(a)(1)(i) of this chapter, and cetyl and stearyl alcohols meet the specifications in § 172.864(a)(1)(ii) of this chapter.

(2) *Conditions of use.* (i) Synthetic fatty alcohols as substitutes for the corresponding naturally derived fatty alcohols permitted for use in compliance with § 178.3910.

(ii) Synthetic lauryl alcohol as a substitute for the naturally derived lauryl alcohol permitted as an intermediate in the synthesis of sodium lauryl sulfate used in compliance with § 178.3400.

§ 178.3500 Glycerin, synthetic.

Synthetic glycerin may be safely used as a component of articles intended for use in packaging materials for food, subject to the provisions of this section:

(a) It is produced by the hydrogenolysis of carbohydrates, and shall contain not in excess of 0.2 percent by weight of a mixture of butanetriols.

(b) It is used in a quantity not to exceed that amount reasonably required to produce its intended physical or technical effect, and in accordance with any limitations prescribed by applicable regulations in Parts 174, 175, 176, 177, 178 and 179 of this chapter. It shall not be intended to, nor in fact accomplish, any direct physical or technical effect in the food itself.

§ 178.3520 Industrial starch-modified.

Industrial starch-modified may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) Industrial starch-modified is identified as follows:

(1) A food starch-modified or starch or any combination thereof that has been modified by treatment with one of the reactants hereinafter specified, in an amount reasonably required to achieve the desired functional effect but in no event in excess of any limitation prescribed, with or without subsequent treatment as authorized in § 172.892 of this chapter.

List of reactants	*Limitations*
Ammonium persulfate, not to exceed 0.3 pct. or in alkaline starch not to exceed 0.6 pct.	
(4 - Chlorobutene - 2) trimethylammonium chloride, not to exceed 5 pct.	Industrial starch modified by this treatment shall be used only as internal sizing for paper and paperboard intended for food packaging.
β-Diethylaminoethyl chloride hydrochloride, not to exceed 4 pct.	
Dimethylaminoethyl methacrylate, not to exceed 3 pct.	
Dimethylol ethylene urea, not to exceed 0.375 pct.	Industrial starch modified by this treatment shall be used only as internal sizing for paper and paperboard intended for food packaging.
2,3 - Epoxypropyltrimethylammonium chloride, not to exceed 5 pct.	
Ethylene oxide, not to exceed 3 pct of reacted ethylene oxide in finished product.	
Phosphoric acid, not to exceed 6 pct and urea, not to exceed 20 pct.	Industrial starch modified by this treatment shall be used only as internal sizing for paper and paperboard intended for food packaging and as surface sizing and coating for paper and paperboard that contact food only of types IV-A, V, VII, VIII, and IX described in table 1 of § 176.170(c) of this chapter.

(2) A starch irradiated under one of the following conditions to produce free radicals for subsequent graft polymerization with the reactants listed in this paragraph (a)(2):

(i) Radiation from a sealed cobalt 60 source, maximum absorbed dose not to exceed 5.0 megarads.

(ii) An electron beam source at a maximum energy of 7 million electron volts of ionizing radiation, maximum absorbed dose not to exceed 5.0 megarads.

List of reactants	*Limitations*
Acrylamide and [2-(methacryloyloxy) ethyl]trimethylammonium methyl sulfate, such that the finished industrial starch-modified shall contain: 1. Not more than 60 weight percent vinyl copolymer (of which not more than 32 weight percent is [2-(methacryloyloxy) ethyl] trimethylammonium methyl sulfate). 2. Not more than 0.20 pct residual acrylamide. 3. A minimum nitrogen content of 9.0 pct.	For use only: 1. As a retention aid and dry strength agent employed before the sheet-forming operation in the manufacture of paper and paperboard intended to contact only dry food of the type identified in § 176.170 (c) of this chapter, table 1 under type VIII, and used at a level not to exceed 0.40 pct by weight of the finished dry paper and paperboard fibers. 2. As a retention aid and dry strength agent employed before the sheet-forming operation in the manufacture of paper and paperboard intended to contact food, and used at a level not to exceed 0.25 pct by weight of the finished dry paper and paperboard fibers.

(b) The following adjuvants may be used as surface-active agents in the processing of industrial starch-modified:

Polyethylene glycol (400) dilaurate.
Polyethylene glycol (400) monolaurate.
Polyoxyethylene (4) lauryl ether.

(c) To insure safe use of the industrial starch-modified, the label of the food additive container shall bear the name of the additive "industrial starch-modified," and in the instance of an industrial starch-modified which is limited with respect to conditions of use, the label of the food additive container shall contain a statement of such limited use.

§ 178.3530 Isoparaffinic petroleum hydrocarbons, synthetic.

Isoparaffinic petroleum hydrocarbons, synthetic, may be safely used in the production of nonfood articles intended for use in producing manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The isoparaffinic petroleum hydrocarbons, produced by synthesis from petroleum gases consist of a mixture of liquid hydrocarbons meeting the following specifications:

Boiling point 145°–500° F, as determined by A.S.T.M. Method D–86.

Ultraviolet absorbance:
260–319 millimicrons—1.5 maximum.
320–329 millimicrons—0.08 maximum.
330–350 millimicrons—0.05 maximum.
Nonvolatile residue 0.002 gram per 100 milliliters maximum.

Synthetic isoparaffinic petroleum hydrocarbons containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. The ultraviolet absorbance shall be determined by the procedure described for application to mineral oil under "Specifications" on page 66 of the Journal of the Association of Official Agricultural Chemists, Vol. 45 (February 1962), disregarding the last sentence of that procedure. For hydrocarbons boiling below 250° F, the nonvolatile residue shall be determined by A.S.T.M. procedure D–1353; for those boiling above 250° F, A.S.T.M. procedure D–381 shall be used.

(b) Isoparaffinic petroleum hydrocarbons may contain antioxidants authorized for use in food in an amount not to exceed that reasonably required to accomplish the intended technical effect.

(c) Isoparaffinic petroleum hydrocarbons are used in the production of nonfood articles. The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect, and the residual remaining in the finished article shall be the minimum amount reasonably attainable.

§ 178.3550 Kaolin-modified.

Kaolin-modified, as identified in this section, may be safely used in olefin polymers as articles or components of articles intended for use in contact with food, subject to the provisions of this section.

(a) Kaolin-modified is produced by treating kaolin with a reaction product of isopropyl titanate and oleic acid in which 1 mole of isopropyl titanate is reacted with 1 to 2 moles of oleic acid. The reaction product will not exceed 8 percent of the modified kaolin. The oleic acid used shall meet the requirements specified in § 172.860 of this chapter.

(b) The additive is used as a pigment, colorant, or opacifier in olefin polymers complying with § 177.1520 of this chapter at levels not to exceed 40 percent by weight of the olefin polymer.

§ 178.3570 Lubricants with incidental food contact.

Lubricants with incidental food contact may be safely used on machinery used for producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

(a) The lubricants are prepared from one or more of the following substances:

(1) Substances generally recognized as safe for use in food.

(2) Substances used in accordance with the provisions of a prior sanction or approval.

(3) Substances identified in this paragraph (a) (3).

Substances	*Limitations*
Aluminum stearoyl benzoyl hydroxide.	For use only as a thickening agent in mineral oil lubricants at a level not to exceed 10 pct by weight of the mineral oil.
BHA	
BHT	
Castor oil	Addition to food not to exceed 10 parts per million.
Castor oil, dehydrated	Do.
Castor oil, partially dehydrated	Do.
Dialkyldimethylammonium aluminum silicate where the alkyl groups are derived from hydrogenated tallow fatty acids (C_{16}–C_{18}) and where the aluminum silicate is derived from bentonite.	For use only as a gelling agent in mineral oil lubricants at a level not to exceed 7 pct by weight of the mineral oil.
Dimethylpolysiloxane (viscosity greater than 300 centistokes).	Addition to food not to exceed 1 part per million.
Fatty acids derived from animal or vegetable sources, and the hydrogenated forms of such fatty acids.	
12-Hydroxystearic acid	
Isopropyl oleate	For use only as an adjuvant (to improve lubricity) in mineral oil lubricants.
Magnesium ricinoleate	For use only as an adjuvant in mineral oil lubricants at a level not to exceed 10 percent by weight of the mineral oil.
Mineral oil	Addition to food not to exceed 10 parts per million.
Petrolatum	Complying with § 178.3700. Addition to food not to exceed 10 parts per million.
Phenyl-α-and/or phenyl-β-naphthylamine.	For use only, singly or in combination, as antioxidant in mineral oil lubricants at a level not to exceed a total of 1 percent by weight of the mineral oil.
Polyurea, having a nitrogen content of 9–14 percent based on the dry polyurea weight, produced by reacting tolylene diisocyanate with tall oil fatty acid (C_{18} and C_{18}) amine and ethylene diamine in a 2:2:1 molar ratio.	For use only as an adjuvant in mineral oil lubricants at a level not to exceed 10 percent by weight of the mineral oil.
Polybutene (minimum average molecular weight 80,000).	Addition to food not to exceed 10 parts per million.
Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740.	Do.
Polyethylene	Do.
Polyisobutylene (average molecular weight 35,000–140,000 (Flory)).	For use only as a thickening agent in mineral oil lubricants.
Sodium nitrite	For use only as a rust preventive in mineral oil lubricants at a level not to exceed 3 percent by weight of the mineral oil.

(b) The lubricants are used on food-processing equipment as a protective antirust film, as a release agent on gaskets or seals of tank closures, and as a lubricant for machine parts and equipment in locations in which there is exposure of the lubricated part to food. The amount used is the minimum required to accomplish the desired technical effect on the equipment, and the addition to food of any constituent identified in this section does not exceed the limitations prescribed.

(c) Any substance employed in the production of the lubricants described in this section that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

§ 178.3600 Methyl glucoside-coconut oil ester.

Methyl glucoside-coconut oil ester identified in § 172.816(a) of this chapter may be safely used as a processing aid (filter aid) in the manufacture of starch, including industrial starch-modified complying with § 178.3520, intended for use as a component of articles that contact food.

§ 178.3610 α-Methylstyrene-vinyltoluene resins, hydrogenated.

Hydrogenated α-methylstyrene-vinyltoluene copolymer resins having a molar ratio of 1 α-methylstyrene to 3 vinyltoluene may be safely used as components of polyolefin film intended for use in contact with food, subject to the following provisions:

(a) Hydrogenated α-methylstyrene-vinyltoluene copolymer resins have a drop-softening point of 125° to 165° C and a maximum absorptivity of 0.17 liter per gram centimeter at 266 nanometers, as determined by methods available upon request from the Commissioner of Food and Drugs.

(b) The polyolefin film is produced from olefin polymers complying with § 177.1520 of this chapter, and the average thickness of the film in the form in which it contacts food does not exceed 0.002 inch.

§ 178.3620 Mineral oil.

Mineral oil may be safely used as a component of nonfood articles intended for use in contact with food, subject to the provisions of this section:

(a) White mineral oil meeting the specifications prescribed in § 172.878 of this chapter may be used as a component of nonfood articles provided such use complies with any applicable limitations in Parts 178 through 189 of this chapter. The use of white mineral oil in or on food itself, including the use of white mineral oil as a protective coating or release agent for food, is subject to the provisions of § 172.878 of this chapter.

(b) Technical white mineral oil identified in paragraph (b) (1) of this section may be used as provided in paragraph (b) (2) of this section.

(1) Technical white mineral oil consists of specially refined distillates of virgin petroleum or of specially refined distillates that are produced synthetically from petroleum gases. Technical

white mineral oil meets the following specifications:

(i) Saybolt color 20 minimum as determined by ASTM Method D-156.

(ii) Ultraviolet absorbance limits as follows:

Wavelength ($m\mu$):	*Maximum absorbance per centimeter optical pathlength*
280 to 289	4.0
290 to 299	3.3
300 to 329	2.3
330 to 350	0.8

Technical white mineral oil containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. The ultraviolet absorbance shall be determined by the procedure described for application to mineral oil under "Specification" on page 66 of the Journal of the Association of Official Agriculture Chemists, Volume 45 (February 1962), disregarding the last two sentences of that procedure and substituting therefor the following: Determine the absorbance of the mineral oil extract in a 10-millimeter cell in the range from 260–350 $m\mu$, inclusive, compared to the solvent control. If the absorbance so measured exceeds 2.0 at any point in range 280–350 $m\mu$, inclusive, dilute the extract and the solvent control, respectively, to twice their volume with dimethyl sulfoxide and remeasure the absorbance. Multiply the remeasured absorbance values by 2 to determine the absorbance of the mineral oil extract per centimeter optical pathlength.

(2) Technical white mineral oil may be used wherever mineral oil is permitted for use as a component of nonfood articles complying with §§ 175.105, 176.200, 176.210, 177.2260, 177.2600, and 177.2800 of this chapter and §§ 178.3570 and 178.-3910.

(3) Technical white mineral oil may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the act, in an amount not greater than that required to produce its intended effect.

(c) Mineral oil identified in paragraph (c) (1) of this section may be used as provided in paragraph (c) (2) of this section.

(1) The mineral oil consists of virgin petroleum distillates refined to meet the following specifications:

(i) Initial boiling point of 450° F minimum.

(ii) Color 5.5 maximum as determined by ASTM Method D-1500.

(iii) Ultraviolet absorbance limits as follows as determined by the analytical method described in paragraph (c) (3) of this section:

Wavelength ($m\mu$):	*Maximum absorbance per centimeter optical pathlength*
280 to 289	0.7
290 to 299	.6
300 to 359	.4
360 to 400	.09

(2) The mineral oil may be used wherever mineral oil is permitted for use as a component of nonfood articles complying with §§ 175.105 and 176.210 of this chapter and § 178.3910 (for use only in rolling of metallic foil and sheet stock), §§ 176.200, 177.2260, 177.2600, and 177.2800 of this chapter.

(3) The analytical method for determining ultraviolet absorbance limit is as follows:

GENERAL INSTRUCTIONS

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of oil samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

Separatory funnels. 250-milliliter, 500-milliliter, 1,000-milliliter, and preferably 2,000-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Reservoir. 500-milliliter capacity, equipped with a 24/40 standard taper male fitting at the bottom and a suitable ball-joint at the top for connecting to the nitrogen supply. The male fitting should be equipped with glass hooks.

Chromatographic tube. 180 millimeters in lenth, inside diameter to be 15.7 millimeters ±0.1 millimeter, equipped with a coarse, fritted-glass disc, a tetrafluoroethylene polymer stopcock, and a female 24/40 standard tapered fitting at the opposite end. (Overall length of the column with the female joint is 235 millimeters.) The female fitting should be equipped with glass hooks.

Disc. Tetrafluoroethylene polymer 2-inch diameter disk approximately $\frac{1}{8}$-inch thick with a hole bored in the center to closely fit the stem of the chromatographic tube.

Suction flask. 250-milliliter or 500-milliliter filter flask.

Condenser. 24/40 joints, fitted with a drying tube, length optional.

Evaporation flask (optional). 250-milliliter or 500-milliliter capacity all-class flask equipped with standard taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of contained liquid to be evaporated.

Spectrophotometric cells. Fused quartz cells, optical path length in the range of 5.000 centimeter ±0.005 centimeter; also for checking spectrophotometer performance only, optical path length in the range 1.000 centimeter ±0.005 centimter. With distilled water in the cells, determine any absorbance differences.

Spectrophotometer. Spectral range 250 millimicrons—400 millimicrons with spectral slit width of 2 millimicrons or less; under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Absorbance accuracy,[1] ±0.005 at 0.4 absorbance.

Wavelength accuracy, ±1.0 millimicron.

Wavelength accuracy, +1.0 millimicron.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

REGENTS AND MATERIALS

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane, benzene, acetone, and methyl alcohol designated in the list following this paragraph shall pass the following test:

To the specified quantity of solvent in a 250-milliliter Erlenmeyer flask, add 1 milliliter of purified *n*-hexadecane and evaporate on the steam bath under a stream of nitrogen (a loose aluminum foil jacket around the flask will speed evaporation). Discontinue evaporation when not over 1 milliliter of residue remains. (To the residue from benzene add a 10-milliliter portion of purified isooctane, reevaporate, and repeat once to insure complete removal of benzene.)

Alternatively, the evaporation time can be reduced by using the optional evaporation flask. In this case the solvent and *n*-hexadecane are placed in the flask on the steam bath, the tube assembly is inserted, and a stream of nitrogen is fed through the inlet tube while the outlet tube is connected to a solvent trap and vacuum line in such a way as to prevent any flow-back of condensate into the flask.

Dissolve the 1 milliliter of hexadecane residue in isooctane and make to 25 milliliters volume. Determine the absorbance in the 5-centimeter path length cells compared to isooctane as reference. The absorbance of the solution of the solvent residue (except for methyl alcohol) shall not exceed 0.01 per centimeter path length between 280 and 400 $m\mu$. For methyl alcohol this absorbance value shall be 0.00.

Isooctane (2,2,4-trimethylpentane). Use 180 milliliters for the test described in the preceding paragraph. Purify, if necessary, by passage through a column of activated silica gel (Grade 12, Davison Chemical Company, Baltimore, Maryland, or equivalent) about 90 centimeters in length and 5 centimeters to 8 centimeters in diameter.

Benzene, A.C.S. reagent grade. Use 150 milliliters for the test. Purify, if necessary, by distillation or otherwise.

Acetone, A.C.S. reagent grade. Use 200 milliliters for the test. Purify, if necessary, by distillation.

Eluting mixtures:

1. *10 percent benzene in isooctane.* Pipet 50 milliliters of benzene into a 250-milliliter glass-stoppered volumetric flask and adjust to volume with isooctane, with mixing.

2. *20 percent benzene in isooctane.* Pipet 50 milliliters of benzene into a 250-milliter glass-stopped volumetric flask and adjust to volume with isooctane, with mixing.

3. *Acetone-benzene-water mixture.* Add 20 milliliters of water to 380 milliliters of acetone and 200 milliliters of benzene, and mix.

n-Hexadecane, 99-percent olefin-free. Dilute 1.0 milliliter of *n*-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 5-centimeter cell compared to isooctane as reference point between 280 $m\mu$-400 $m\mu$. The absorbance per centimeter path length shall not exceed 0.00 in this range. Purify, if necessary, by percolation through activated silica gel or by distillation.

Methyl alcohol, A.C.S. reagent grade. Use 10.0 milliliters of methyl alcohol. Purify, if necessary, by distillation.

Dimethyl sulfoxide. Spectrophotometric grade (Crown Zellerbach Corporation, Camas, Washington, or equivalent). Absorbance

[1] As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484. Spectrophotometry, U.S. Department of Commerce, 1949. The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons.

(1-centimeter cell, distilled water reference, sample completely saturated with nitrogen).

Wavelength:	*Absorbance (maximum)*
261.5	1.00
270	.20
275	.09
280	.06
300	.015

There shall be no irregularities in the absorbance curve within these wavelengths.

Phosphoric acid. 85 percent A.C.S. reagent grade.

Sodium borohydride. 98 percent.

Magnesium oxide (Sea Sorb 43, Food Machinery Company, Westvaco Division, distributed by chemical supply firms, or equivalent). Place 100 grams of the magnesium oxide in a large beaker, add 700 milliliters of distilled water to make a thin slurry, and heat on a steam bath for 30 minutes with intermittent stirring. Stir well initially to insure that all the adsorbent is completely wetted. Using a Buchner funnel and a filter paper (Schleicher & Schuell No. 597, or equivalent) of suitable diameter, filter with suction. Continue suction until water no longer drips from the funnel. Transfer the adsorbent to a glass trough lined with aluminum foil (free from rolling oil). Break up the magnesia with a clean spatula and spread out the adsorbent on the aluminum foil in a layer about 1 centimeter to 2 centimeters thick. Dry for 24 hours at 160° C ±1° C. Pulverize the magnesia with mortar and pestle. Sieve the pulverized adsorbent between 60–180 mesh. Use the magnesia retained on the 180-mesh sieve.

Celite 545. Johns Mansville Company, diatomaceous earth, or equivalent.

Magnesium oxide-Celite 545 mixture (2+1) by weight. Place the magnesium oxide (60–180 mesh) and the Celite 545 in 2 to 1 proportions, respectively, by weight in a glass-stoppered flask large enough for adequate mixing. Shake vigorously for 10 minutes. Transfer the mixture to a glass trough lined with aluminum foil (free from rolling oil) and spread it out on a layer about 1 centimeter to 2 centimeters thick. Reheat the mixture at 160° C ±1° C for 2 hours, and store in a tightly closed flask.

Sodium sulfate, anhydrous, A.C.S. reagent grade, preferably in granular form. For each bottle of sodium sulfate reagent used, establish as follows the necessary sodium sulfate prewash to provide such filters required in the method: Place approximately 35 grams of anhydrous sodium sulfate in a 30-milliliter course, fritted-glass funnel or in a 65-millimeter filter funnel with glass wool plug; wash with successive 15-milliliter portions of the indicated sovent until a 15-milliliter portion of the wash shows 0.00 absorbance per centimeter path length between 280 m_μ and 400 m_μ when tested as prescribed under "Organic solvents." Usually three portions of wash solvent are sufficient.

Before proceeding with analysis of a sample, determine the absorbance in a 5-centimeter path cell between 250 millimicrons and 400 millimicrons for the reagent blank by carrying out the procedure, without an oil sample, recording the spectra after the extraction stage and after the complete procedure as prescribed. The absorbance per centimeter path length following the extraction stage should not exceed 0.02 in the wavelength range from 280 m_μ to 400 m_μ; the absorbance per centimeter path length following the complete procedure should not exceed 0.02 in the wavelength range from 280 m_μ to 400 m_μ. If in either spectrum the characteristic benzene peaks in the 250 m_μ–260 m_μ region are present, remove the benzene by the procedure under "Organic solvents" and record absorbance again.

Place 300 milliliters of dimethyl sulfoxide in a 1-liter separatory funnel and add 75 milliliters of phosphoric acid. Mix the contents of the funnel and allow to stand for 10 minutes. (The reaction between the sulfoxide and the acid is exothermic. Release pressure after mixing, then keep funnel stoppered.) Add 150 milliliters of isooctane and shake to pre-equilibrate the solvents. Draw off the individual layers and store in glass-stoppered flasks.

Weigh a 20-gram sample of the oil and transfer to a 500-milliliter separatory funnel containing 100 milliliters of pre-equilibrated sulfoxide-phosphoric acid mixture. Complete the transfer of the sample with small portions of preequilibrated isooctane to give a total volume of the oil and solvent of 75 milliliters. Shake the funnel vigorously for 2 minutes. Set up three 250-milliliter separatory funnels with each containing 30 milliliters of pre-equilibrated isooctane. After separation of liquid phases, carefully draw off lower layer into the first 250-milliliter separatory funnel and wash in tandem with the 30-milliliter portions of isooctane contained in the 250-milliliter separatory funnels. Shaking time for each wash is 1 minute. Repeat the extraction operation with two additional portions of the sulfoxide-acid mixture and wash each extractive in tandem through the same three portions of isooctane

Collect the successive extractives (300 milliliters total) in a separatory funnel (preferably 2-liter) containing 480 milliliters of distilled water; mix, and allow to cool for a few minutes after the last extractive has been added. Add 80 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second separatory funnel (preferably 2-liter) and repeat the extraction with 80 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 80-milliliter extractives three times with 100-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see Sodium sulfate under "Reagents and Materials" for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the first separatory funnel with the second 80-milliliter isooctane extractive and pass through the sodium sulfate. Then wash the second and first separatory funnels successively with a 20-milliliter portion of isooctane and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of *n*-hexadecane and evaporate the isooctane on the steam bath under nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10-milliliter portion of isooctane, re-evaporate to 1 milliliter of hexadecane, and repeat this operation once.

Quantitatively transfer the residue with isooctane to a 200-milliliter volumetric flask, make to volume, and mix. Determine the absorbance of the solution in the 1-centimeter pathlength cells compared to isooctane as reference between 280 m_μ–400 m_μ (take care to lose none of the solution in filling the sample cell). Correct the absorbance values for any absorbance derived from reagents as determined by carrying out the procedure without an oil sample. If the corrected absorbance does not exceed the limits prescribed in this paragraph, the oil meets the ultraviolet absorbance specifications. If the corrected absorbance per centimeter pathlength exceeds the limits prescribed in this paragraph, proceed as follows: Quantitatively transfer the isooctane solution to a 125-milliliter flask equipped with 24/40 joint, and evaporate the isooctane on the steam bath under a stream of nitrogen to a volume of 1 milliliter of hexadecane. Add 10 milliliters of methyl alcohol and approximately 0.3 gram of sodium borohydride. (Minimize exposure of the borohydride to the atmosphere. A measuring dipper may be used.) Immediately fit a water-cooled condenser equipped with a 24/40 joint and with a drying tube into the flask, mix until the borohydride is dissolved, and allow to stand for 30 minutes at room temperature, with intermittent swirling. At the end of this period, disconnect the flask and evaporate the methyl alcohol on the steam bath under nitrogen until the sodium borohydride begins to come out of the solution. Then add 10 milliliters of isooctane and evaporate to a volume of about 2–3 milliliters. Again, add 10 milliliters of isooctane and concentrate to a volume of approximately 5 milliliters. Swirl the flask repeatedly to assure adequate washing of the sodium borohydride residues.

Fit the tetrafluoroethylene polymer disc on the upper part of the stem of the chromatographic tube, then place the tube with the disc on the suction flask and apply the vacuum (approximately 135 millimeters Hg pressure). Weigh out 14 grams of the 2:1 magnesium oxide-Celite 545 mixture and pour the adsorbent mixture into the chromatographic tube in approximately 3-centimeter layers. After the addition of each layer, level off the top of the adsorbent with a flat glass rod or metal plunger by pressing down firmly until the adsorbent is well packed. Loosen the topmost few millimeters of each adsorbent layer with the end of a metal rod before the addition of the next layer. Continue packing in this manner until all the 14 grams of the adsorbent is added to the tube. Level off the top of the adsorbent by pressing down firmly with a flat glass rod or metal plunger to make the depth of the adsorbent bed approximately 12.5 centimeters in depth. Turn off the vacuum and remove the suction flask. Fit the 500-milliliter reservoir onto the top of the chromatographic column and prewet the column by passing 100 milliliters of isooctane through the column. Adjust the nitrogen pressure so that the rate of descent of the isooctane coming off the column is between 2–3 milliliters per minute. Discontinue pressure just before the last of the isooctane reaches the level of the adsorbent. (Caution: Do not allow the liquid level to recede below the adsorbent level at any time.) Remove the reservoir and decant the 5-milliliter isooctane concentrate solution onto the column and with slight pressure again allow the liquid level to recede to barely above the adsorbent level. Rapidly complete the transfer similarly with two 5-milliliter portions of isooctane, swirling the flask repeatedly each time to assure adequate washing of the residue. Just before the final 5-milliliter wash reaches the top of the adsorbent, add 100 milliliters of isooctane to the reservoir and continue the percolation at the 2–3 milliliters per minute rate. Just before the last of the isooctane reaches the adsorbent level, add 100 milliliters of 10 percent benzene in isooctane to the reservoir and continue the percolation at the aforementioned rate. Just before the solvent mixture reaches adsorbent level, add 25 milliliters of 20 percent benzene in isooctane to the reservoir and continue the percolation at 2–3 milliliters per minute until all this solvent mixture has been removed from the column. Discard all the elution solvents collected up to this point. Add 300 milliliters of the acetone-benzene-water mixture to the reservoir and percolate through the column to eluate the polynuclear compounds. Collect the eluate in a clean 1-liter separatory funnel. Allow the column to drain until most of the solvent mixture is removed. Wash the eluate three

times with 300-milliliter portions of distilled water, shaking well for each wash. (The addition of small amounts of sodium chloride facilitates separation.) Discard the aqueous layer after each wash. After the final separation, filter the residual benzene through anhydrous sodium sulfate pre-washed with benzene (see Sodium sulfate under "Reagents and Materials" for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the separatory funnel with two additional 20-milliliter portions of benzene which are also filtered through the sodium sulfate. Add 1 milliliter of *n*-hexadecane and completely remove the benzene by evaporation under nitrogen, using the special procedure to eliminate benzene as previously described under "Organic solvents." Quantitatively transfer the residue with isooctane to a 200-milliliter volumetric flask and adjust to volume. Determine the absorbance of the solution in the 1-centimeter pathlength cells compared to isooctane as reference between 250 mμ–400 mμ. Correct for any absorbance derived from the reagents as determined by carrying out the procedure without an oil sample. If either spectrum shows the characteristic benzene peaks in the 250 mμ–260 mμ region, evaporate the solution to remove benzene by the procedure under "Organic solvents." Dissolve the residue, transfer quantitatively, and adjust to volume in isooctane in a 200-milliliter volumetric flask. Record the absorbance again. If the corrected absorbance does not exceed the limits proposed in this paragraph, the oil meets the proposed ultraviolet absorbance specifications.

(d) Mineral oil identified in paragraph (d)(1) of this section may be used as provided in paragraph (d)(2) of this section.

(1) The mineral oil consists of virgin petroleum distillates refined to meet the following specifications:

(i) Distillation endpoint at 760 millimeters pressure not to exceed 700° F, with a maximum residue not to exceed 2 percent, as determined by ASTM Method D 86–IP 123.

(ii) Ultraviolet absorbance limits as follows as determined by the method described in paragraph (d)(3) of this section.

Wavelength (mμ):	*Maximum absorbance per centimeter optical pathlength*
280 to 299	2.3
300 to 319	1.2
320 to 359	.8
360 to 400	.3

(iii) Pyrene content not to exceed a maximum of 25 parts per million as determined by the method described in paragraph (d)(3) of this section.

(2) The mineral oil may be used only in the processing of jute fiber employed in the production of textile bags intended for use in contact with the following types of food: Dry grains and dry seeds (for example, beans, peas, rice, and lentils); whole root crop vegetables of the types identified in 40 CFR 180.34 (f); unshelled and shelled nuts (including peanuts); and dry animal feed. The finished processed jute fiber shall contain no more than 6 percent by weight of residual mineral oil.

(3) The analytical method for determining ultraviolet absorbance limits and pyrene content is as follows:

I. *Apparatus.* A. Assorted beakers, separatory funnels fitted with tetrafluoroethylene polymer stopcocks, and graduated cylinders.

B. Volumetric flasks, 200-milliliter.

C. A chromatographic column made from nominal 1.3 centimeters outside diameter x 75 centimeters glass tubing tapered at one end and joined to a 2-millimeter-bore tetrafluorethylene polymer stopcock. The opposite end is flanged and joined to a female 24/40 standard taper fitting. This provides for accommodating the 500-milliliter reservoir described in item E below.

D. A chromatographic column made from nominal 1.7 centimetrs outside diameter x 115 centimeters glass tubing tapered at one end and joined to a 2-millimeter-bore tetrafluorethylene polymer stopcock. The opposite end is flanged and joined to a 2.5 centimeters outside diameter x 9.0 centimeters glass tube having a female 24/40 standard taper fitting. This provides for accommodating the 500-milliliter reservoir described in item I. E below.

E. A 500-milliliter reservoir having a 24/40 standard taper male fitting at bottom and a suitable ball joint at the top for connecting to the nitrogen supply. The female fitting of the chromatographic columns described in items I. C and D above and the male fitting of the reservoir described in this item E should both be equipped with glass hooks.

(NOTE: Rubber stoppers are not to be used. Stopcock grease is not to be used on ground-glass joints in this method.)

F. A spectrophotometer equipped to automatically record absorbance of liquid samples in 1-centimeter pathlength cells in the spectral region of 280–400 mμ with a spectral slit width of 2 mμ or less. At an absorbance level of about 0.4, absorbance measurements shall be repeatable within ±0.01 and accurate within ±0.05. Wavelength measurements shall be repeatable with ±0.2 mμ and accurate within ±1.0 mμ. Instrument operating conditions are selected to realize this performance under dynamic (automatic) recording operations. Accuracy of absorbance measurements are determined at 290, 345, and 400 mμ, using potassium chromate as the reference standard. (National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, 1949.)

G. Two fused quartz cells having pathlengths of 1.00±0.005 centimeter or better.

II. *Purity of reagents and materials.* Reagent-grade chemicals shall be used in all tests. It is further specified that each chemical shall be tested for purity in accordance with the instruction given under "Reagents and Materials" in III below. In addition, a blank run by the procedure shall be made on each purified lot of reagents and materials. Unless otherwise indicated, references to water shall be understood to mean distilled water.

III. *Reagents and materials — A. Organic solvents.* All solvents used throughout the procedure shall meet the specifications and tests described in this section III. The isooctane, benzene, cyclohexane, nitromethane, and *n*-hexadecane designated shall pass the following test: To the specified quantity of solvent in a 150-milliliter beaker, add 1 milliliter of purified *n*-hexadecane and evaporate on the steam bath under a stream of nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains (to the residue from benzene and nitromethane add a 10-milliliter portion of purified isooctane, re-evaporate, and repeat once to insure complete removal of solvent). Dissolve the 1 milliliter of *n*-hexadecane residue in isooctane and make to 10-milliliter volume. Determine the absorbance in 1.0-centimeter pathlength cells compared to water as reference. The absorbance of the solution of solvent residue shall not exceed 0.05 between 280 and 400 mμ.

1. *Isooctane (2,2,4-trimethylpentane).* Use 240 milliliters for the above test. Purify, if necessary, by passage through a column of activated silica gel.

2. *Benzene.* Use 200 milliliters for the above test. Purify, if necessary, by distillation or otherwise.

3. *Cyclohexane.* Use 70 milliliters for the above test. Purify, if necessary, by distillation, silica gel percolation, or otherwise.

4. *Nitromethane.* Use 125 milliliters for the above test. Purify, if necessary, by distillation or otherwise.

5. *n-Hexadecane.* Determine the absorbance on this solvent directly. Purify, if necessary, by silica gel percolation or otherwise.

B. *Other materials—1. Pyrene standard reference.* Pyrene, reagent grade, melting point range 150–152° C. (Organic Chemical 3627, Eastman Kodak Co., Rochester, N.Y., or equivalent). The standard reference absorbance is the absorbance at 334 millimicrons of a standard reference solution of pyrene containing a concentration of 1.0 milligram per liter in purified isooctane measured against isooctane of the same spectral purity in 1.0-centimeter cells. (This absorbance will be approximately 0.28.)

2. *Chrysene solution.* Prepare a solution at a concentration of 5.0 milligrams per liter by dissolving 5.0 milligrams of chrysene in purified isooctane in a 1-liter volumetric flask. Adjust to volume with isooctane.

3. *Nitrogen gas.* Water pumped or equivalent purity, cylinder with regulator, and valve control flow at 5 p.s.i.

4. *Silica gel.* 100–200 mesh (Davison Chemical, Baltimore, Md., Grade 923, or equivalent), purified and activated by the following procedure: Place about 1 kilogram of silica gel in a large column and wash with contaminant-free benzene until a 200-milliliter sample of the benzene coming off the column will pass the ultraviolet absorption test for benzene. This test is performed as stipulated under "Organic solvents" in A under III above. When the silica gel has been sufficiently cleaned, activate the gel before use by placing the 1-kilogram batch in a shallow container in a layer no greater than 1 inch in depth and heating in an oven (Caution! Explosion Hazard) at 130° C. for 16 hours, and store in a vacuum desiccator. Reheating about once a week is necessary if the silica gel is repeatedly removed from the desiccator.

5. *Aluminum oxide (Aluminum Co. of America, Grade F–20, or equivalent grade).* 80–200 mesh, purified and activated by the following procedure: Place about 1 kilogram of aluminum oxide in a large column and wash with contaminant-free benzene until a 200-milliliter sample of the benzene coming off the column will pass the ultraviolet absorption test for benzene. This test is performed as stipulated under "Organic solvents" in A under III above. (Caution! Remove Benzene From Adsorbent Under Vacuum To Minimize Explosion Hazard in Subsequent Heating!) When the aluminum oxide has been sufficiently cleaned and freed of solvent, activate it before use by placing the 1-kilogram batch in a shallow container in a layer no greater than 1 inch in depth. Heat in a oven at 130° C for 16 hours. Upon removal from heat, store at atmospheric pressure over 60 percent (by weight) sulfuric acid in a desiccator for at least 36 hours before use. This gives aluminum oxide with between 6 to 9.5 percent volatiles. This is determined by heating a weighed sample of the prepared aluminum oxide at 2,000° F for 2 hours and then quickly reweighing. To insure the proper adsorptive properties of the aluminum oxide, perform the following test:

a. Weigh 50 grams ±1 gram of the activated aluminum oxide and pack into the chromatographic column (1.3 centimeters x 75 centimeters) described under "Apparatus" in C under I above. Use glass wool at the column exit to prevent the aluminum oxide from passing through the column.

b. Place a 250-milliliter graduated cylinder under the column to measure the amount of eluate coming from the column.

c. Prewet the aluminum oxide by passing 40 milliliters of isooctane through the column. Adjust the nitrogen pressure so that the rate of descent of the isooctane coming off the column is between 1.5 to 2.5 milliliters per minute.

d. Just prior to the last of the isooctane reaching the top of the aluminum oxide bed, add 10 milliliters of the isooctane solution containing 5.0 milligrams of chrysene per liter.

e. Continue percolation until the isooctane is just above the aluminum oxide. Then add 200 milliliters of a mixture of benzene and isooctane (33⅓ percent benzene and 66⅔ percent isooctane by volume) to the reservoir and continue percolation.

f. Continue percolation, collecting the eluates (40 milliliters of the prewet solution, 10 milliliters of the sample solution, and 200 milliliters of the gradient solution) in the 250-milliliter graduated cylinder until the level of the gradient solution is just above the aluminum oxide. Add 200 milliliters of the eluting solution of benzene and isooctane (90 percent benzene and 10 percent isooctane by volume) to the column and continue collecting until a total of 250 milliliters of solution has been obtained. This may be discarded. Now begin to collect the final eluate.

g. Place a 100-milliliter graduated cylinder under the column and continue the percolation until a 100-milliliter eluate has been obtained.

h. Measure the amount of chrysene in this 100-milliliter fraction by ultraviolet analysis. If the aluminum oxide is satisfactory, more than 80 percent of the original amount of chrysene should be found in this fraction. (NOTE: If the amount of chrysene recovered is less than 80 percent, the original batch of aluminum oxide should be sieved between 100–160 mesh. Activation and testing of this sieved batch should indicate a satisfactory aluminum oxide for use.)

IV. *Sampling.* Precautions must be taken to insure that an uncontaminated sample of the mineral oil is obtained since ultraviolet absorption is very sensitive to small amounts of extraneous material contaminating the sample through careless handling.

V. *Procedure.* A. *Blank.* Before proceeding with the analysis of a sample, determine the absorbance of the solvent residues by carrying out the procedure without a sample.

B. *Sample.* 1. Weigh out 20.0 grams ±0.1 gram of the mineral oil into a beaker and transfer to a 250-milliliter separatory funnel fitted with a tetrafluoroethylene polymer stopcock, using enough cyclohexane (25 milliliters) to give a final total volume of 50 milliliters (mineral oil plus cyclohexane).

2. Add 25 milliliters of nitromethane saturated with cyclohexane and shake by hand vigorously for 3 minutes. Recover the lower nitromethane layer in a 150-milliliter beaker containing 1 milliliter of *n*-hexadecane and evaporate on the steam bath under nitrogen. Repeat the extraction four more times, recovering each extract in the 150-milliliter beaker. Exercise care not to fill the beaker to such a capacity that solvent losses may occur. Evaporate the combined nitromethane extracts to 1 milliliter of *n*-hexadecane residue containing the nitromethane-soluble mineral oil extractives. (NOTE: Complete removal of the nitromethane is essential. This can be assured by two successive additions of 5 milliliters of isooctane and reevaporation.)

3. Remove the beaker from the steam bath and allow to cool.

4. Weigh 50 grams ±1 gram of activated aluminum oxide and pack into the chromatographic column (1.3 centimeters x 75 centimeters) described under "Apparatus" in C under I above. (NOTE: A small plug of glass wool is placed at the column exit to prevent the aluminum oxide from passing through the column. After adding aluminum oxide, tap the column lightly to remove air voids. All percolations using aluminum oxide are performed under nitrogen pressure. The 500-milliliter reservoir described under "Apparatus" in E under I above is to be used to hold the elution solvents.)

5. Prewet the column by adding 40 milliliters of isooctane to the column. Adjust nitrogen pressure so that rate of descent of the isooctane coming off the column is 2.0 to 3.0 milliliters per minute. Be careful to maintain the level of solvent in the reservoir to prevent air from entering the aluminum oxide bed. New or additional solvent is added just before the last portion of the previous solvent enters the bed. To minimize possible photo-oxidation effects, the following procedures (steps 6 through 18) shall be carried out in subdued light.

6. Before the last of the isooctane reaches the top of the aluminum oxide bed, release the nitrogen pressure and turn off the stopcock on the column. Transfer the *n*-hexadecane residue from the 150-milliliter beaker from procedure step 3 above onto the column, using several washes of isooctane (total volume of washes should be no greater than 10–15 milliliters).

7. Open the stopcock and continue percolation until the isooctane is about 1 centimeter above the top of the aluminum oxide bed. Add 200 milliliters of isooctane to the reservoir, and continue the percolation at the specified rate.

8. Just before the isooctane surface reaches the top of the aluminum oxide bed, add 200 milliliters of a mixture of benzene and isooctane (33⅓ percent benzene and 66⅔ percent isooctane by volume) to the reservoir, and continue the percolation.

9. Just before the surface of this mixture reaches the top of the aluminum oxide bed, release the nitrogen pressure, turn off the stopcock, and discard all the elution solvents collected up to this point.

10. Add to the reservoir 300 milliliters of a mixture of benzene and isooctane (90 percent benzene and 10 percent isooctane by volume), place a 25-milliliter graduated cylinder under the column, continue the percolation until 20 milliliters of eluate has been collected, and then discard the eluate.

11. At this point, place a clean 250-milliliter Erlenmeyer flask under the column. Continue the percolation and collect all the remaining eluate.

(NOTE: Allow the column to drain completely. An increase in the nitrogen pressure may be necessary as the last of the solvent comes off the column.)

12. Place 1 milliliter of *n*-hexadecane into a 150-milliliter beaker. Place this onto a steam bath under a nitrogen stream and transfer in small portions the eluate from step 11 above. Wash out the Erlenmeyer flask with small amounts of benzene and transfer to the evaporation beaker. Evaporate until only 1 milliliter of hexadecane residue remains. (NOTE: Complete removal of the benzene is essential. This can be assured by two successive additions of 5 milliliters of isooctane and reevaporation.)

13. Remove the beaker from the steam bath and cool.

14. Place a sample of 113.5 grams activated 100- 200-mesh silica gel in a 500-milliliter glass-stoppered Erlenmeyer flask. Add to the silica gel 46.2 grams (41 milliliters) of nitromethane. Stopper and shake the flask vigorously until no lumps of silica gel are observed and then shake occasionally during a period of 1 hour. The resultant nitromethane-treated silica gel is 29 weight-percent nitromethane and 71 weight-percent silica gel.

15. Place a small plug of glass wool in the tapered end of the 1.7 centimeters outside diameter x 115 centimeters column, described under "Apparatus" in D of I above, adjacent to the stopcock to prevent silica gel from passing through the stopcock. Pack the nitromethane-treated silica gel into the column, tapping lightly. The resultant silica gel bed should be about 95 centimeters in depth. Place into a flask 170 milliliters of isooctane saturated with nitromethane.

16. Place a 100-milliliter graduated cylinder under the column and transfer the residue from the beaker in procedure step 13 above with several washes of the 170 milliliters of isooctane, saturated with nitromethane, onto the top of the column. (Total volume of washes should be no greater than 10 to 15 milliliters.) Permit isooctane solution to enter the silica gel bed until the liquid level is at the top bed level. Place the remaining amount of the 170 milliliters of isooctane, saturated with nitromethane, in the reservoir above the bed for percolation through the silica gel. Apply nitrogen pressure to the top of the column, adjusting the pressure so that the isooctane is collected at the rate of 2.5 to 3.5 milliliters per minute, and percolate isooctane through the bed until a quantity of 75.0 milliliters of eluate is collected. Discard the 75 milliliters of eluate. Turn off the stopcock and add 250 milliliters of benzene to the reservoir above the bed. Use a 400-milliliter beaker to collect the remaining eluate.

17. Open the stopcock, renew the pressure, and percolate the remaining isooctane and benzene through the column eluting the remaining aromatics. Transfer the eluate in small portions from the 400 milliliter beaker to a 150-milliliter beaker containing 1 milliliter of *n*-hexadecane and evaporate on the steam bath under nitrogen. Rinse the 400-milliliter beaker well with small portions of isooctane to obtain a complete transfer.

(NOTE: Complete removal of the nitromethane and benzene is essential. This can be assured by successive additions of 5 milliliters of isooctane and reevaporation.)

18. Transfer the residue with several washes of isooctane into a 200-milliliter volumetric flask. Add isooctane to mark.

19. Record the spectrum of the sample solution in a 1-centimeter cell compared to isooctane from 270 to 400 mμ. After making necessary corrections in the spectrum for cell differences and for the blank absorbance, record the maximum absorbance in each of the wavelength intervals (mμ), 280–299, 300–319, 320–359, 360–400.

a. If the spectrum then shows no discernible peak corresponding to the absorbance maximum of the pyrene reference standard solution at 334 mμ, the maximum absorbances in the respective wavelength intervals recorded shall not exceed those prescribed in paragraph (d)(1)(ii) of this section.

b. If such a peak is evident in the spectrum of the sample solution, and the spectrum as a whole is not incompatible with that of a pyrene contaminant yielding such a peak of the observed absorbance, calculate the concentration of pyrene that would yield this peak (334 mμ) by the base-line technique described in ASTM Method E–169–60T. Correct each of the maximum absorbances in the respective specified wavelength intervals

by subtracting the absorbance due to pyrene, determined as follows:

$$\text{Absorbance due to pyrene} = \frac{Cp \times Sa}{Sp}$$

Where:

Cp = Calculated concentration of pyrene in sample solution;
Sp = Concentration of pyrene reference standard solution in same units of concentration;
Sa = Absorbance of pyrene reference standard solution at wavelength of maximum absorbance of sample solution in the respective specified wavelength intervals.

Also calculate the pyrene content of the oil sample in parts per million as follows:

$$\text{Pyrene content (p.p.m.)} = \frac{200/1000 \times C}{20/1000} = 10C.$$

Where:

C = Calculated concentration of pyrene in milligrams per liter of sample solution.

c. The pyrene content so determined shall not exceed 25 p.p.m. The maximum absorbances corrected for pyrene content as described in this step 19 for each of the specified wavelength intervals shall not exceed the limits prescribed in paragraph (d)(1)(ii) of this section.

d. If the spectrum as a whole of the sample solution is in any respect clearly incompatible with the presence of pyrene as the source of the peak at 334 $m\mu$, then the maximum absorbances in the respective wavelength intervals without correction for any assumed pyrene content shall not exceed the limits prescribed in paragraph (d)(1)(ii) of this section.

§ 178.3650 Odorless light petroleum hydrocarbons.

Odorless light petroleum hydrocarbons may be safely used, as a component of nonfood articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) The additive is a mixture of liquid hydrocarbons derived from petroleum or synthesized from petroleum gases. The additive is chiefly paraffinic, isoparaffinic, or naphthenic in nature.

(b) The additive meets the following specifications:

(1) Odor is faint and not kerosenic.

(2) Initial boiling point is 300° F minimum.

(3) Final boiling point is 650° F maximum.

(4) Ultraviolet absorbance limits determined by method specified in § 178.3620(b)(1)(ii), as follows:

Wavelength ($M\mu$):	*Maximum absorbance per centimeter optical pathlength*
280 to 289	4.0
290 to 299	3.3
300 to 329	2.3
330 to 360	.8

(c) The additive is used as follows:

Use	*Limitations*
As a plasticizer and absorber oil in the manufacture of polyolefin articles authorized for food contact use.	In an amount not to exceed that required to produce intended effect, consistent with good manufacturing practice.
As a lubricant of fibers of textiles authorized for food contact use.	At a use level not to exceed 0.15 percent by weight of finished fibers.
As a component of adhesives	Complying with § 175.105 of this chapter.
As a defoamer in the manufacture of paper and paperboard.	Complying with § 176.210 of this chapter.
As a defoamer in coatings	Complying with § 176.200 of this chapter.

§ 178.3700 Petrolatum.

Petrolatum may be safely used as a component of nonfood articles in contact with food, in accordance with the following conditions:

(a) Petrolatum complies with the specifications set forth in the U.S. Pharmacopeia XVII for white petrolatum or in The National Formulary XII for yellow petrolatum.

(b) Petrolatum meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in § 172.886(b) of this chapter:

Ultraviolet absorbance per centimeter path length:

Millimicrons:	*Maximum*
280 to 289	0.25
290 to 299	.20
300 to 359	.14
360 to 400	.04

(c) It is used or intended for use as a protective coating of the surfaces of metal or wood tanks used in fermentation process, in an amount not in excess of that required to produce its intended effect.

(d) Petrolatum as defined by this section may be used for the functions described and within the limitations prescribed by specific regulations in Parts 175, 176, 177, and 178 of this chapter which prescribe uses of petrolatum. For the purpose of cross-reference, such specific regulations include: §§ 175.105, 175, 176, 177, and 178 of this chapter 177.2600, and 177.2800 of this chapter and § 178.3570.

(e) Petrolatum may contain any antioxidant permitted in food by regulations issued pursuant to section 409 of the act, in an amount not greater than that required to produce its intended effect.

§ 178.3710 Petroleum wax.

Petroleum wax may be safely used as a component of nonfood articles in contact with food, in accordance with the following conditions:

(a) Petroleum wax is a mixture of solid hydrocarbons, paraffinic in nature, derived from petroleum, and refined to meet the specifications prescribed in this section.

(b) The petroleum wax meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in § 172.886(b) of this chapter.

Ultraviolet absorbance per centimeter path length:

Millimicrons:	*Maximum*
280 to 289	0.15
290 to 299	.12
300 to 359	.08
360 to 400	.02

(c) Petroleum wax may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the act, in an amount not greater than that required to produce its intended effect.

(d) Petroleum wax may contain a total of not more than 1 weight percent of residues of the following polymers when such residues result from use of the polymers as processing aids (filter aids) in the production of the petroleum wax. Homopolymers and/or copolymers derived from one or more of the mixed *n*-alkyl (C_{12}, C_{14}, C_{16}, and C_{18}) methacrylate esters where the C_{12} and C_{14} alkyl groups are derived from coconut oil and the C_{16} and C_{18} groups are derived from tallow.

(e) Petroleum wax may contain 2-hydroxy-4-*n*-octoxybenzophenone as a stabilizer at a level not to exceed 0.01 weight percent of the petroleum wax.

§ 178.3720 Petroleum wax, synthetic.

Synthetic petroleum wax may be safely used in applications and under the same conditions where naturally derived petroleum wax is permitted in Subchapter B of this chapter as a component of articles intended to contact food, provided that the synthetic petroleum wax meets the definition and specifications prescribed in § 172.888 of this chapter.

§ 178.3730 Piperonyl butoxide and pyrethrins as components of bags.

Piperonyl butoxide in combination with pyrethrins may be safely used for insect control on bags that are intended for use in contact with dried feed in compliance with §§ 561.310 and 561.340 of this chapter, or that are intended for use

in contact with dried food in compliance with §§ 193.60 and 193.390 of this chapter.

§ 178.3740 Plasticizers in polymeric substances.

Subject to the provisions of this regulation, the substances listed in paragraph (b) of this section may be safely used as plasticizers in polymeric substances used in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

(a) The quantity used shall not exceed the amount reasonably required to accompish the intended technical effect.

(b) List of substances:

Substances	*Limitations*
Butylbenzyl phthalate	For use only: 1. As provided in §§ 175.105 and 176.180 of this chapter. 2. In polymeric substances used in food-contact articles complying with §§ 175.300, 175.320, or 176.170 of this chapter: *Provided*, That the butyl benzyl phthalate contains not more than 1 percent by weight of dibenzyl phthalate. 3. In polymeric substances used in other permitted food-contact articles: *Provided*, That the butyl benzyl phthalate contains not more than 1 percent by weight of dibenzyl phthalate; and *Provided further*, That the finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of § 175.300(d) of this chapter, shall yield net chloroform-soluble extractives not to exceed 0.5 mg. per square inch, as determined by the methods prescribed in § 175.300(e) of this chapter.
1,3-Butylene glycoladipic acid polyester (1,700–2,200 molecular weight) terminated with a 16 percent by weight mixture of myristic, palmitic, and stearic acids.	For use at levels not exceeding 33 percent by weight of polyvinyl chloride homopolymers used in contact with food (except foods that contain more than 8 percent of alcohol) at temperatures not to exceed room temperature. The average thickness of such homopolymers in the form in which they contact food shall not exceed 0.004 inch.
Di(C_7, C_9-alkyl) adipate, in which the C_7, C_9 alkyl groups are derived from linear alpha olefins by the oxo process.	For use only under the conditions listed below, and excluding use as a component of resinous and polymeric coatings described in § 175.300 of this chapter. 1. At levels not to exceed 24 percent by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. 2. At levels not to exceed 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in table 2 of § 176.170(c) of this chapter, with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. 3. At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymer in the form in which they contact food shall not exceed 0.002 inch. 4. At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in table 2 of § 176.170(c) of this chapter with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch.
Di-*n*-alkyl adipate made from C_6-C_8-C_{10} (predominately C_8 and C_{10}) or C_8-C_{10} synthetic fatty alcohols complying with § 172.864 of this chapter.	For use only: 1. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. 2. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in table 2 of § 176.170(c) of this chapter, with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. 3. At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch. 4. At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in table 2 of § 176.170(c) of this chapter, with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in which they contact food shall not exceed 0.002 inch.
Dicyclohexyl phthalate	For use only: 1. As provided in §§ 175.105, 176.170, 176.180, and 177.1200 of this chapter. 2. Alone or in combination with other phthalates, in plastic film or sheet prepared from polyvinyl acetate, polyvinyl chloride, and/or viny chloride copolymers complying with § 177.1980 of this chapter. Such plastic film or sheet shall be used in contact with food at temperatures not to exceed room temperature and shall contain no more than 10 pct by weight of total phthalates, calculated as phthalic acid.
Di(2-ethylhexyl) adipate Diisononyl adipate	For use only: 1. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty, nonalcoholic foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. 2. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact under conditions of use F and G described in table 2 of § 176.170(c) of this chapter with fatty, nonalcoholic foods having a fat and oil content not exceeding a total of 30 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. 3. At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty, nonalcoholic foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch. 4. At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in table 2 of § 176.170(c) of this chapter with fatty, nonalcoholic foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch.

Substances	Limitations
Diisononyl phthalate	For use only at levels not exceeding 43 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with food only of the types identified in § 176.170(c) of this chapter, Table 1, under categories I, II, IV–B, and VIII, at temperatures not exceeding room temperature. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch.
Di(2-ethylhexyl) azelate	For use only: 1. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty, nonalcoholic food. The average thickness of such polymers in the form in which they contact food shall not exceed 0.003 inch. 2. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in table 2 of § 175.170(c) of this chapter, with fatty, nonalcoholic food having a fat and oil content not exceeding a total of 30 percent by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.003 inch.
Di-n-hexyl azelate	For use only: 1. In polymeric substances used in contact with nonfatty food. 2. In polymeric substances used in contact with fatty food and limited to use at levels not exceeding 15 pct by weight of such polymeric substance except as provided under limitation 3. 3. At levels greater than 15 but not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F or G described in table 2 of § 176.170(c) of this chapter, with fatty food having a fat and oil content not exceeding a total of 30 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.003 inch.
Dihexyl phthalate	For use only: 1. As provided in § 175.105 of this chapter. 2. In articles that contact food only of the types identified in § 176.170(c) of this chapter, table 1, under categories I, II, IV–B, VI–B, and VIII.
Diphenyl phthalate	For use only: 1. As provided in § 175.105 of this chapter. 2. Alone or in combination with other phthalates, in plastic film or sheet prepared from polyvinyl acetate, polyvinyl chloride, and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. Such plastic film or sheet shall be used in contact with food at temperatures not to exceed room temperature and shall contain no more than 10 pct by weight of total phthalates, calculated as phthalic acid.
Epoxidized butyl esters of linseed oil fatty acids.	Iodine number, maximum 5; oxirane oxygen, minimum 7.8 pct.
Epoxidized linseed oil	Iodine number, maximum 5; oxirane oxygen, minimum 9 pct.
Mineral oil, white	
Polybutene, hydrogenated (minimum viscosity at 210° F. 39 Saybolt Universal seconds, as determined by ASTM Methods D–445 and D–2161; and bromine number of 3 or less, as determined by ASTM Method D–1492).	For use only: 1. In polymeric substances used in contact with non-fatty food. 2. In polyethylene complying with § 177.1520 of this chapter and used in contact with fatty food, provided that the hydrogenated polybutene is added in an amount not to exceed 0.5 pct by weight of the polyethylene, and further provided that such plasticized polyethylene shall not be used as a component of articles intended for packing or holding food during cooking. 3. In polystyrene complying with § 177.1640 of this chapter and used in contact with fatty food, provided that the hydrogenated polybutene is added in an amount not to exceed 5 pct by weight of the polystyrene, and further provided that such plasticized polystyrene shall not be used as a component of articles intended for packing or holding food during cooking.
Polyisobutylene (mol weight 300–5,000).	For use in polyethylene complying with § 177.1520 of this chapter, provided that the polyisobutylene is added in an amount not exceeding 0.5 pct by weight of the polyethylene, and further provided that such plasticized polyethylene shall not be used as a component of articles intended for packing or holding food during cooking.
Polyisobutylene complying with § 177.1420 of this chapter.	
Propylene glycol azelate (average mol. weight 3,000).	For use only at levels not exceeding 41 pct by weight of permitted polyvinyl chloride coatings. Such coatings shall be used only as bulk food contact surfaces of articles intended for repeated use, complying with § 177.2600 of this chapter.
Triethylene glycol	Diethylene glycol content not to exceed 0.1 pct.
2,2,4-Trimethyl-1, 3-pentanediol diisobutyrate.	For use only in cellulosic plastics in an amount not to exceed 15 pct by weight of the finished food-contact article, provided that the finished plastic article contacts food only of the types identified in § 176.170(c) of this chapter, table 1, under categories I, II, VI–B, VII–B, and VIII.

(c) The use of the plasticizers in any polymeric substance or article subject to any regulation in Parts 174, 175, 176, 177, 178 179 of this chapter must comply with any specifications and limitations prescribed by such regulation for the finished form of the substance or article.

§ 178.3750 Polyethylene glycol (mean molecular weight 200–9,500).

Polyethylene glycol identified in this section may be safely used as a component of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) The additive is an addition polymer of ethylene oxide and water with a mean molecular weight of 200 to 9,500.

(b) It contains no more than 0.2 percent total by weight of ethylene and diethylene glycols if its mean molecular weight is 350 or higher and no more than 0.5 percent total by weight of ethylene and diethylene glycols if its mean molecular weight is below 350, when tested by the analytical methods prescribed in § 172.820(b) of this chapter.

(c) The provisions of paragraph (b) of this section are not applicable to polyethylene glycols used in food-packaging adhesives complying with § 175.105 of this chapter.

§ 178.3760 Polyethylene glycol (400) monolaurate.

Polyethylene glycol (400) monolaurate containing not more than 0.1 percent by weight of ethylene and/or diethylene glycol may be used at a level not to exceed 0.3 percent by weight of twine as a finish on twine to be used for tying meat provided the twine fibers are produced from nylon resins complying with § 177.1500 of this chapter.

§ 178.3770 Polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids.

Polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids identified in this section may be safely used as components of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) The polyhydric alcohol diesters identified in this paragraph may be used as lubricants in the fabrication of vinyl chloride plastic food-contact articles prepared from polyvinyl chloride and/or from vinyl chloride copolymers complying with § 177.1980 of this chapter. Such diesters meet the following specifications and are produced by partial esterification of oxidatively refined (Gersthoffen process) montan wax acids by either ethylene glycol or 1,3-butanediol with or without neutralization of unreacted carboxylic groups with calcium hydroxide:

(1) Dropping point 76° —105° C, as determined by ASTM Method D 566.

(2) Acid value 10–20, as determined by ASTM Method D 1386 using as solvent xylene-ethyl alcohol in a 2:1 ratio instead of toluene-ethyl alcohol in a 1:2 ratio.

(3) Saponification value 100–160, as determined by ASTM Method D 1387 using xylene-ethyl alcohol in a 2:1 ratio instead of ethyl alcohol in preparation of potassium hydroxide solution.

(4) Ultraviolet absorbance limits as follows, as determined by the analytical method described in this subparagraph:

Ultraviolet absorbance per centimeter path length.

Millimicrons:	Maximum
280 to 289	0.07
290 to 299	.06
300 to 359	.04
360 to 400	.01

ANALYTICAL METHOD

GENERAL INSTRUCTIONS

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of wax samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

Separatory funnels. 250-milliliter, 500-milliliter, 1,000-milliliter, and preferably 2,000-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Reservoir. 1,000-milliliter capacity, equipped with a 24/40 standard taper male fitting at the bottom and a suitable ball-joint at the top.

Chromatographic tube. 1,200 millimeters in length, inside diameter to be 16.5 millimeters

±0.5 millimeter, equipped with a coarse, fritted-glass [illegible], a tetrafluoroethylene polymer stopcock, and a female 24/40 standard tapered fitting at the opposite end. (Overall length of the column with the female joint is 1,255 millimeters.) The female fitting should be equipped with glass hooks.

Disc. Tetrafluoroethylene polymer 2-inch diameter disc approximately 5/16-inch thick with a hole bored in the center to closely fit the stem of the chromatographic tube.

Heating jackets. Conical, for 500-milliliter and 1,000-milliliter separatory funnels. (Used with variable transformer heat control.)

Suction flask. 250-milliliter or 500-milliliter filter flask.

Condenser. 24/40 joints, fitted with a drying tube, length optional.

Evaporation flasks (optional). A 250-milliliter or 500-milliliter capacity and a 1-liter capacity all-glass flask equipped with standard taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of contained liquid to be evaporated.

Vacuum distillation assembly. All glass (for purification of dimethyl sulfoxide) 2-liter distillation flask with heating mantle; Vigreaux vacuum-jacketed condenser (or equivalent) about 45 centimeters in length and distilling head with separable cold finger condenser. Use of tetrafluoroethylene polymer sleeves on the glass joints will prevent freezing. Do not use grease on stopcocks or joints.

Oil bath. Capable of heating to 90° C.

Spectrophotometric cells. Fused quartz cells, optical path length in the range 1.000 centimeter ±0.005 centimeter. With distilled water in the cells, determine any absorbance differences.

Spectrophotometer. Spectral range 250 millimicrons–400 millimicrons with spectral slit width of 0.2 millimicron or less; under instrument operating conditions for these absorbance measurements. The spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Absorbance accuracy,[1] ±0.05 at 0.4 absorbance.

Wavelength repeatability, ±0.2 millimicron.

Wavelength accuracy, ±1.0 millimicron.

Recording time, 50 seconds.

Time constant, 0.6 second.

Sensitivity, 30.

Ordinate scale, 90–100 percent transmission through scale.

Abscissa scale, 8X.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

Reagents and Materials

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane and benzene designated in the list following this paragraph shall pass the following test:

To the specified quantity of solvent in a 250-milliliter Erlenmeyer flask, add 1 milliliter of purified *n*-hexadecane and evaporate on the steam bath under a stream of nitrogen (a loose aluminum foil jacket around the flask will speed evaporation). Discontinue evaporation when not over 1 milliliter of residue remains. (To the residue from benzene add a 10-milliliter portion of purified isooctane, reevaporate, and repeat once to insure complete removal of benzene.)

Alternatively, the evaporation time can be reduced by using the optional evaporation flask. In this case the solvent and *n*-hexadecane are placed in the flask on the steam bath, the tube assembly is inserted, and a stream of nitrogen is fed through the inlet tube while the outlet tube is connected to a solvent trap and vacuum line in such a way as to prevent any flow-back of condensate into the flask.

Dissolve the 1 milliliter of hexadecane residue in isooctane and make up to 25 milliliters volume. Determine the absorbance in the 1-centimeter path length cells compared to isooctane as reference. The absorbance of the solution of the solvent residue (except for methyl alcohol) shall not exceed 0.01 per centimeter path length between 280 mμ and 400 mμ.

Isooctane (2,2,4-trimethylpentane). Use 180 milliliters for the test described in the preceding paragraph. Purify, if necessary, by passage through a column of activated silica gel (Grade 12, Davison Chemical Co., Baltimore, Md., or equivalent) about 90 centimeters in length and 5 centimeters to 8 centimeters in diameter.

Benzene, A.C.S. reagent grade. Use 150 milliliters for the test. Purify, if necessary, by distillation or otherwise.

n-Hexadecane, 99 percent olefin-free. Dilute 1.0 milliliter of *n*-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 1-centimeter cell compared to isooctane as reference point between 280 mμ–400 mμ. The absorbance per centimeter path length shall not exceed 0.00 in this range. If necessary, purify by filtering through a column containing 100 grams of aluminum oxide (use same grade as described below) in the lower half and 100 grams of activated silica gel in the upper half keeping the column at 150° C., for a period of 15 hours or overnight. The first 100 milliliters of eluate are used. Purification can also be accomplished by distillation.

Dimethyl sulfoxide. Pure grade, clear, water-white, m.p. 1° minimum. Dilute 120 milliliters of dimethyl sulfoxide with 240 milliliters of distilled water in a 500-milliliter separatory funnel, mix and allow to cool for 5–10 minutes. Add 40 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second 500-milliliter separatory funnel and repeat the extraction with 40 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 40-milliliter extractives three times with 50-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see *Sodium sulfate* under "Reagents and materials" for preparation of filter), into a 250-milliliter Erlenmeyer flask, or optionally into the evaporating flask. Wash the first separatory funnel with the second 40-milliliter isooctane extractive, and pass through the sodium sulfate into the flask. Then wash the second and first separatory funnels successively with a 10-milliliter portion of isooctane, and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of *n*-hexadecane and evaporate the isooctane on the steam bath under nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10-milliliter portion of isooctane and reevaporate to 1 milliliter of hexadecane. Again, add 10 milliliters of isooctane to the residue and evaporate to 1 milliliter of hexadecane to insure complete removal of all volatile materials. Dissolve the 1 milliliter of hexadecane in isooctane and make to 25-milliliter volume. Determine the absorbance in 1-centimeter path length cells compared to isooctane as reference. The absorbance of the solution should not exceed 0.02 per centimeter path length in the 280 mμ–400 mμ range. (Note: Difficulty in meeting this absorbance specification may be due to organic impurities in the distilled water. Repetition of the test omitting the dimethyl sulfoxide will disclose their presence. If necessary to meet the specification, purify the water by redistillation, passage through an ion-exchange resin, or otherwise.)

Purify, if necessary, by the following procedure: To 1,500 milliliters of dimethyl sulfoxide in a 2-liter glass-stoppered flask, add 6.0 milliliters of phosphoric acid and 50 grams of Norit A (decolorizing carbon, alkaline) or equivalent. Stopper the flask, and with the use of a magnetic stirrer (tetrafluoroethylene polymer coated bar) stir the solvent for 15 minutes. Filter the dimethyl sulfoxide through four thicknesses of fluted paper (18.5 centimeters, Schleicher & Schuell, No. 597, or equivalent). If the initial filtrate contains carbon fines, refilter through the same filter until a clear filtrate is obtained. Protect the sulfoxide from air and moisture during this operation by covering the solvent in the funnel and collection flask with a layer of isooctane. Transfer the filtrate to a 2-liter separatory funnel and draw off the dimethyl sulfoxide into the 2-liter distillation flask of the vacuum distillation assembly and distill at approximately 3-millimeter Hg pressure or less. Discard the first 200-milliliter fraction of the distillate and replace the distillate collection flask with a clean one. Continue the distillation until approximately 1 liter of the sulfoxide has been collected.

At completion of the distillation, the reagent should be stored in glass-stoppered bottles since it is very hygroscopic and will react with some metal containers in the presence of air.

Phosphoric acid. 85 percent A.C.S. reagent grade.

Aluminum oxide (80–200 mesh Woelm neutral activity grade 1 [Brockmann], Alupharm Chemicals, New Orleans, La., or equivalent). Pipette 1 milliliter of distilled water into a dry 250-milliliter Erlenmeyer flask equipped with a ground-glass stopper. Stopper the flask and rotate it in such a manner as to completely wet out the inside surfaces. When this has been done add 180 grams of the aluminum oxide and shake until no lumps or wet spots remain. Allow to stand at room temperature for a period of 2 hours. At the end of this time the water should be evenly distributed throughout the aluminum oxide powder, and it should have the same free flowing properties as the original material (flow velocity with water 0.2 milliliter per minute). At this point the aluminum oxide has an activity of 1 as expressed in Brockmann degrees, and the amount of added water is 0.5 percent by volume. This product is used in toto and as is, without further screening.

Sodium sulfate, anhydrous, A.C.S. reagent grade, preferably in granular form. For each bottle of sodium sulfate reagent used, establish as follows the necessary sodium sulfate prewash to provide such filters required in the method: Place approximately 35 grams of anhydrous sodium sulfate in a 30-milliliter coarse, fritted-glass funnel or in a 65-millimeter filter funnel with glass wool plug; wash with successive 15-milliliter portions of the indicated solvent until a 15-milliliter portion of the wash shows 0.00 absorbance per centimeter path length between 280 mμ

[1] As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, "Spectrohpotometry," U.S. Department of Commerce, 1949. The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons.

and 400 mμ when tested as prescribed under "Organic solvents." Usually three portions of wash solvent are sufficient.

PROCEDURE

Before proceeding with analysis of a sample, determine the absorbance in a 1-centimeter path cell between 250 mμ and 400 mμ for the reagent blank by carrying out the procedure, without a wax sample, at room temperature, recording the spectrum after the complete procedure as prescribed. The absorbance per centimeter path length following the complete procedure should not exceed 0.04 in the wavelength range from 280 mμ to 299 mμ, inclusive, nor 0.02 in the wavelength range from 300 mμ to 400 mμ. If in either spectrum the characteristic benzene peaks in the 250 mμ–260 mμ region are present, remove the benzene by the procedure under "Organic solvents" and record absorbance again.

Place 300 milliliters of dimethyl sulfoxide in a 1-liter separatory funnel and add 75 milliliters of phosphoric acid. Mix the contents of the funnel and allow to stand for 10 minutes. (The reaction between the sulfoxide and the acid is exothermic. Release pressure after mixing, then keep funnel stoppered.) Add 150 milliliters of isooctane and shake to preequilibrate the solvents. Draw off the individual layers and store in glass-stoppered flasks.

In a 1-liter separatory funnel place a representative 25-gram sample of wax, add 50 milliliters of isooctane, heat gently, stir until the wax is in solution; add 100 milliliters of preequilibrated sulfoxide-phosphoric acid mixture and shake, making sure it remains in solution. If the wax comes out of solution during these operations, let the stoppered funnel remain in the jacket until the wax redissolves. (Remove stopper from the funnel at intervals to release pressure.) When the wax is in solution, remove the funnel from the jacket and shake it vigorously for 2 minutes. Set up three 250-milliliter separatory funnels with each containing 30 milliliters of preequilibrated isooctane. After separation of the liquid phases, allow to cool until the main portion of the wax-isooctane solution begins to show a precipitate. Gently swirl the funnel when precipitation first occurs on the inside surface of the funnel to accelerate this process. Carefully draw off the lower layer, filter it slowly through a thin layer of glass wool fitted loosely in a filter funnel into the first 250-milliliter separatory funnel, and wash in tandem with the 30-milliliter portions of isooctane contained in the 250-milliliter separatory funnels. Shaking time for each wash is 1 minute. Repeat the extraction operation with two additional portions of the sulfoxide-acid mixture, replacing the funnel in the jacket after each extraction to keep the wax in solution and washing each extractive in tandem through the same three portions of isooctane.

Collect the successive extractives (300 milliliters total) in a separatory funnel (preferably 2-liter), containing 480 milliliters of distilled water, mix, and allow to cool for a few minutes after the last extractive has been added. Add 80 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second separatory funnel (preferably 2-liter) and repeat the extraction with 80 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 80-milliliter extractives three times with 100-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see *Sodium sulfate* under "Reagents and Materials" for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the first separatory funnel with the second 80-milliliter isooctane extractive and pass through the sodium sulfate. Then wash the second and first separatory funnels successively with a 20-milliliter portion of isooctane and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of *n*-hexadecane and evaporate the isooctane using an aspirator vacuum under nitrogen and in an oil bath temperature of approximately 90° C. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10-milliliter portion of isooctane, reevaporate to 1 milliliter of hexadecane, and repeat this operation once.

Reserve the residue for column chromatography on the aluminum oxide.

Fit the tetrafluoroethylene polymer disc on the upper part of the stem of the chromatographic tube, then place the tube with the disc on the suction flask and apply the vacuum (approximately 135 millimeters Hg pressure). Weigh out 180 grams of the aluminum oxide and pour the adsorbent mixture into the chromatographic tube in approximately 30-centimeter layers. After the addition of each layer, level off the top of the adsorbent with a flat glass rod or metal plunger by pressing down firmly until the adsorbent is well packed. Loosen the topmost few millimeters of each adsorbent layer with the end of a metal rod before the addition of the next layer. Continue packing in this manner until all the 180 grams of the adsorbent is added to the tube. Level off the top of the adsorbent by pressing down firmly with a flat glass rod or metal plunger to make the depth of the adsorbent bed approximately 80 centimeters in depth. Turn off the vacuum and remove the suction flask. Dissolve the hexadecane residue in 10 milliliters of warm benzene and decant the solution onto the column and allow the liquid level to recede to barely above the adsorbent level. Rapidly complete the transfer similarly with two 10-milliliter portions of benzene swirling the flask repeatedly each time to assure adequate washing of the residue. Fix the 1,000-milliliter reservoir onto the top of the chromatographic column. Just before the final 10-milliliter wash reaches the top of the adsorbent, add 670 milliliters of benzene to the reservoir and continue the percolation at the 2–3 milliliter per minute rate until a total of 670 milliliters of benzene has been utilized. Collect the eluate in a clean 1-liter Erlenmeyer flask (or optionally into a 1-liter evaporation flask). Allow the column to drain until most of the solvent mixture is removed. Add 1 milliliter of *n*-hexadecane and completely remove the benzene by evaporation under nitrogen, using the special procedure to eliminate benzene as previously described under "Organic Solvents." Quantitatively transfer the residue with isooctane to a 25-milliliter volumetric flask and adjust to volume. Determine the absorbance of the solution in the 1-centimeter path length cells compared to isooctane as reference between 250 mμ–400 mμ. Correct for any absorbance derived from the reagents as determined by carrying out the procedure without a wax sample. If either spectrum shows the characteristic benzene peaks in the 250 mμ–260 mμ region, evaporate the solution to remove benzene by the procedure under "Organic Solvents." Dissolve the residue, transfer quantitatively, and adjust to volume in isooctane in a 25-milliliter volumetric flask. Record the absorbance again. If the corrected absorbance does not exceed the limits prescribed in paragraph (a) of this section, the wax meets the ultraviolet absorbance specifications.

(b) The polyhydric alcohol diesters identified in this paragraph may be used as release agents in resinous and polymeric coatings for polyolefin films complying with § 175.320 of this chapter. Such diesters meet the following specifications and are produced by partial esterification of oxidatively refined (Gersthoffen process) montan wax acids with equimolar proportions of ethylene glycol and 1,3-butanediol:

(1) Dropping point 77°–82° C, as determined by ASTM Method D 566.

(2) Acid value 25–35, as determined by ASTM Method D 1386 using as solvent xylene-ethyl alcohol in a 2:1 ratio instead of toluene-ethyl alcohol in a 1:2 ratio.

(3) Saponification value 135–150, as determined by ASTM Method D 1387 using xylene-ethyl alcohol in a 2:1 ratio instead of ethyl alcohol in preparation of potassium hydroxide solution.

(4) Ultraviolet absorbance limits specified in paragraph (a)(4) of this section, as determined by the analytical method described therein.

§ 178.3780 Polyhydric alcohol esters of long chain monobasic acids.

Polyhydric alcohol esters of long chain monobasic acids identified in this section may be safely used as lubricants in the fabrication of polyvinyl chloride and/or polyvinyl chloride copolymer articles complying with § 177.1980 of this chapter that contact food of types I, II, IV–B, VI–B, VII–B, and VIII identified in table 1 in § 176.170(c) of this chapter under conditions of use E, F, and G described in table 2 in § 176.170(c) of this chapter, subject to the provisions of this section.

(a) *Identity.* For the purpose of this section, polyhydric alcohol esters of long chain monobasic acids consist of polyhydric alcohol esters having number average molecular weights in the range of 1,050 to 1,700. The esters are produced by the reaction of either ethylene glycol or glycerol with long chain monobasic acids containing from 9 to 49 carbon atoms obtained by the ozonization of long chain *alpha*-olefins, the unreacted carboxylic acids in the formation of the glycerol esters being neutralized with calcium hydroxide to produce a composition having up to 2 percent by weight calcium. The *alpha*-olefins, obtained from the polymerization of ethylene, have 20 to 50 carbon atoms and contain a minimum of 75 percent by weight straight chain *alpha*-olefins and not more than 25 percent vinylidene compounds.

(b) *Specifications.* The polyhydric alcohol esters have the following specifications:

(1) Melting point of 60–80° C for the ethylene glycol ester and 90–105° C for the glycerol ester as determined by the Fisher Johns method.

(2) Acid value 15–25 for each ester as determined by the A.O.C.S. Method Tria-64T,[14] modified to use as the acid solvent a 1:1 volume mixture of anhydrous isopropyl alcohol and toluene. The solution is titrated with 0.1*N* methanolic sodium hydroxide.

[14] Copies may be obtained from: American Association of Oil Chemists, 36 East Wacker Dr., Chicago, IL 60601.

(3) Saponification value 120–160 for the ethylene glycol ester and 90–130 for the glycerol ester as determined by an analytical method available upon request from the Division of Food and Color Additives, HFF–330, U.S. Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204.

(4) Ultraviolet absorbance as specified in § 178.3770(a)(4) of this chapter when tested by the analytical method described therein.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788; 21 U.S.C. 321(s), 348, 371 (a).)

§ 178.3790 Polymer modifiers in semirigid and rigid vinyl chloride plastics.

The polymers identified in paragraph (a) of this section may be safely admixed, alone or in mixture with other permitted polymers, as modifiers in semirigid and rigid vinyl chloride plastic food-contact articles prepared from vinyl chloride homopolymers and/or from vinyl chloride copolymers complying with § 177.1950, § 177.1970, and/or § 177.1980 of this chapter, in accordance with the following prescribed conditions:

(a) For the purpose of this section, the polymer modifiers are identified as follows:

(1) Acrylic polymers identified in this subparagraph provided that such polymers contain at least 50 weight-percent of polymer units derived from one or more of the monomers listed in paragraph (a)(1)(i) of this section.

(i) Homopolymers and copolymers of the following monomers:

n-Butyl acrylate.
n-Butyl methacrylate.
Ethyl acrylate.
Methyl methacrylate.

(ii) Copolymers produced by copolymerizing one or more of the monomers listed in paragraph (a)(1)(i) of this section with one or more of the following monomers:

Acrylonitrile.
Butadiene.
α-Methylstyrene.
Styrene.
Vinylidene chloride.

(iii) Polymers identified in paragraph (a)(1)(i) and (ii) of this section containing no more than 5 weight-percent of total polymer units derived by copolymerization with one or more of the following monomers:

Acrylic acid.
1,3-Butylene glycol dimethacrylate.
Divinylbenzene.
Methacrylic acid.

(iv) Mixtures of polymers identified in paragraph (a)(1)(i), (ii), and (iii) of this section; provided that no chemical reactions, other than addition reactions, occur when they are mixed.

(2) Polymers identified in paragraph (a)(1) of this section combined during their polymerization with butadiene-styrene copolymers; provided that no chemical reactions, other than addition reactions, occur when they are combined. Such combined polymers may contain 50 weight-percent or more of total polymer units derived from the butadiene-styrene copolymers.

(b) The polymer content of the finished plastic food-contact article consists of:

(1) Not less than 80 weight-percent of polymer units derived from the vinyl chloride polymers identified in the introduction to this section and not more than 5 weight-percent of polymer units derived from polymers identified in paragraph (a)(1) of this section and may optionally contain up to 15 weight-percent of polymer units derived from butadiene-styrene copolymers; or

(2) Not less than 50 weight-percent of polymer units derived from the vinyl chloride polymers identified in the introduction to this section, not more than 50 weight-percent of polymer units derived from homopolymers and/or copolymers of ethyl acrylate and methyl methacrylate, and not more than 30 weight-percent of polymer units derived from copolymers of methyl methacrylate, α-methylstyrene and acrylonitrile and may optionally contain up to 15 weight-percent of polymer units derived from butadiene-styrene copolymers.

(c) No chemical reactions, other than addition reactions, occur among the vinyl chloride polymers and the modifying polymers present in the polymer mixture used in the manufacture of the finished plastic food-contact article.

(d) The finished plastic food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from Tables 1 and 2 of § 176.170(c) of this chapter, yields extractives not to exceed the limits prescribed in § 177.1010 (b)(1), (2), (3), and (4) of this chapter when tested by the methods prescribed in § 177.1010 (c) of this chapter.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

§ 178.3800 Preservatives for wood.

Preservatives may be safely used on wooden articles that are used or intended for use in packaging, transporting, or holding raw agricultural products subject to the provisions of this section:

(a) The preservatives are prepared from substances identified in paragraph (b) of this section and applied in amounts not to exceed those necessary to accomplish the technical effect of protecting the wood from decay, mildew, and water absorption.

(b) The substances permitted are as follows:

List of substances	*Limitations*
Copper-8-quinolinolate	
Mineral spirits	
Paraffin wax	Used singly or in combination so as to constitute not less than 50% of the solids.
Petroleum hydrocarbon resin, produced by the homo- and copolymerization of dienes and olefins of the aliphatic, alicyclic, and monobenzenoid arylalkene type from distillates of cracked petroleum stocks.	Do.
Pentachlorophenol and its sodium salt	Not to exceed 50 p.p.m. in the treated wood, calculated as pentachlorophenol.
Rosins and rosin derivatives	As provided in § 78.3870.
Zinc salt of sulfonated petroleum	

§ 178.3850 Reinforced wax.

Reinforced wax may be safely used as an article or component of articles intended for use in producing, manufacturing, packing, processing, transporting, or holding food subject to the provisions of this section.

(a) Reinforced wax consists of petroleum wax to which have been added certain optional substances required in its production, or added to impart desired physical or technical properties.

(b) The quantity of any optional adjuvant substance employed in the production of or added to reinforced wax does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation provided in this section.

(c) Any substance employed in the production of reinforced wax, including any optional substance, that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, conforms with any specification in such regulation.

(d) The substances and optional adjuvant substances employed in the production of or added to reinforced wax include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction for use in reinforced wax and used in accordance with such sanction or approval.

(3) Substances identified in this subparagraph and subject to any limitations provided therein:

List of substances	*Limitations*
Copolymer of isobutylene modified with isoprene	
Petroleum wax. Type I and Type II	
Polyethylene	
Rosins and rosin derivatives as provided in § 178.3870	

(e) Reinforced wax conforming with the specifications in this paragraph is used as provided in paragraph (e) (2) of this section.

(1) The chloroform-soluble portion of the water extract obtained by exposing reinforced wax to demineralized water at 70° F for 48 hours shall not exceed 0.5 milligram per square inch of food-contact surface.

(2) It is used as a packaging material or component of packaging materials for cheese and cheese products.

§ 178.3860 Release agents.

Substances listed in paragraph (b) of this section may be safely used as release agents in petroleum wax complying with § 178.3710 and in polymeric resins that contact food, subject to the provisions of this section.

(a) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect or any limitations prescribed in this section.

(b) Release agents:

List of substances:	*Limitations*
Erucamide (erucylamide)	
N,N'-Dioleoylethylenediamine	For use only in polyvinyl chloride films in amounts such that the concentration of the substance in these films in the form in which the films contact food shall not exceed 0.055 milligram of the substance per square inch of film.
Oleyl palmitamide	
Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b).	For use only subject to the limitations prescribed for hydrogenated polybutene under § 178.3740(b).
Saturated fatty acid amides manufactured from fatty acids derived from animal, marine, or vegetable fats and oils.	
Stearyl erucamide	

§ 178.3870 Rosins and rosin derivatives.

The rosins and rosin derivatives identified in paragraph (a) of this section may safely be used in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The rosins and rosin derivatives are identified as follows:

(1) Rosins:

(i) Gum rosin, refined to color grade of K or paler.

(ii) Wood rosin, refined to color grade of K or paler.

(iii) Tall oil rosin, refined to color grade of K or paler.

(iv) Dark tall oil rosin, a fraction resulting from the refining of tall oil rosin produced by multicolumnar distillation of crude tall oil to effect removal of fatty acids and pitch components and having a saponification number of from 110–135 and 32 percent–44 percent rosin acids.

(v) Dark wood rosin, all or part of the residue after the volatile terpene oils are distilled from the oleoresin extracted from pine wood.

(2) Modified rosins manufactured from rosins identified in paragraph (a) (1) of this section:

(i) Partially hydrogenated rosin, catalytically hydrogenated to a maximum refractive index of 1.5012 at 100° C, and a color of WG or paler.

(ii) Fully hydrogenated rosin, catalytically hydrogenated to a maximum dehydroabietic acid content of 2 percent, a minimum drop-softening point of 79° C, and a color of X or paler.

(iii) Partially dimerized rosin, dimerized by sulfuric acid catalyst to a drop-softening point of 95°–105° C and a color of WG or paler.

(iv) Fully dimerized rosin, dimerized by sulfuric acid catalyst, and from which sufficient nondimerized rosin has been removed by distillation to achieve a minimum drop-softening point of 143° C, and a color of H or paler.

(v) Disproportionated rosin, catalytically disproportionated to a minimum dehydroabietic acid content of 35 percent, a maximum abietic acid content of 1 percent, a maximum content of substituted phenanthrenes (as retene) of 0.25 percent, and a color of WG or paler.

(3) Rosin esters manufactured from rosins and modified rosins identified in paragraphs (a) (1) and (2) of this section:

(i) Glycerol ester of wood rosin purified by steam stripping to have an acid number of 3 to 9, a drop-softening point of 88°–96° C, and a color of N or paler.

(ii) Glycerol ester of partially hydrogenated wood rosin, having an acid number of 3 to 10, a drop-softening point of 79°–88° C, and a color of N or paler.

(iii) Glycerol ester of partially dimerized rosin, having an acid number of 3 to 8, a drop-softening point of 109°–119° C, and a color of M or paler.

(iv) Glycerol ester of fully dimerized rosin, having an acid number of 5 to 16, a drop-softening point of 165°–175° C, and a color of H or paler.

(v) Glycerol ester of maleic anhydride-modified wood rosin, having an acid number of 30 to 40, a drop-softening point of 138°–146° C, a color of M or paler, and a saponification number less than 280.

(vi) Methyl ester of rosin, partially hydrogenated, purified by steam stripping to have an acid number of 4 to 8, a refractive index of 1.5170 to 1.5205 at 20° C, and a viscosity of 23 to 66 poises at 25° C.

(vii) Pentaerythritol ester of wood rosin, having an acid number of 6 to 16, a drop-softening point of 109°–116° C, and a color of M or paler.

(viii) Pentaerythritol ester of partially hydrogenated wood rosin, having an acid number of 7 to 18, a drop-softening point of 102°–110° C, and a color of K or paler.

(ix) Pentaerythritol ester of maleic anhydride-modified wood rosin, having an acid number of 8 to 16, a drop-softening point of 154°–162° C, a color of M or paler, and having a saponification number less than 280.

(x) Pentaerythritol ester of maleic anhydride-modified wood rosin, having an acid number of 9 to 16, a drop-softening point of 130°–140° C, a color of N or paler, and having a saponification number less than 280.

(xi) Pentaerythritol ester of maleic anhydride-modified wood rosin, having an acid number of 134 to 145, a drop-softening point of 127°–137° C, a color of M or paler, and having a saponification number less than 280.

(xii) Pentaerythritol ester of maleic anhydride-modified wood rosin, having an acid number of 30 to 40, a drop-softening point of 131°–137° C, a color of N or paler, and having a saponification number less than 280.

(xiii) Pentaerythritol ester of maleic anhydride-modified wood rosin, further modified by reaction with 4,4'-isopropylidenediphenol-formaldehyde condensate, having an acid number of 10 to 22, a drop-softening point of 162°–172° C, a color of K or paler, a saponification number less than 280, and a maximum ultraviolet absorbance of 0.14 at 296 mμ (using a 1-centimeter cell and 200 milligrams of the rosin ester per liter of solvent consisting of ethyl alcohol made alkaline by addition of 0.1 percent of potassium hydroxide).

(xiv) Mixed methyl and pentaerythritol ester of maleic anhydride-modified wood rosin, having an acid number of 73 to 83, a drop-softening point of 113°–123° C, a color of M or paler, and a saponification number less than 280.

(xv) Triethylene glycol ester of partially hydrogenated wood rosin, having an acid number of 2 to 10, a color of K or paler, and a viscosity of 350 to 425 seconds Saybolt at 100° C.

(xvi) Glycerol ester of maleic anhydride-modified wood rosin, having an acid number of 17 to 23, a drop-softening point of 136°–140° C, a color of M or paler, and a saponification number less than 280. For use only in cellophane complying with § 177.1200 of this chapter.

(xvii) Citric acid-modified glycerol ester of rosin, having an acid number less than 20, a drop-softening point of 105°—115° C, and a color of K or paler. For use only as a blending agent in coatings for cellophane complying with § 177.1200 of this chapter.

(xviii) Glycerol ester of tall oil rosin, purified by steam stripping to have an acid number of 5–12, a softening point of 80°—88° C, and a color of N or paler.

(xix) Glycerol ester of maleic anhydride-modified tall oil rosin, having an acid number of 30 to 40, a drop-softening point of 141°—146° C, a color of N or paler, and a saponification number less than 280.

(xx) Glycerol ester of disproportionated tall oil rosin, having an acid number of 5 to 10, a drop-softening point of 84°—93° C, a color of WG or paler, and a saponification number less than 180.

(4) Rosin salts and sizes—Ammonium, calcium, potassium, sodium, or zinc salts

of rosin manufactured by the partial or complete saponification of any one of the rosins or modified rosins identified in paragraph (a) (1) and (2) of this section, or blends thereof, and with or without modification by reaction with one or more of the following:

(i) Formaldehyde.

(ii) Fumaric acid.

(iii) Maleic anhydride.

(iv) Saligenin.

(b) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect.

(c) The use in any substance or article that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter shall conform with any specifications and limitations prescribed by such regulation for the finished form of the substance or article.

(d) The provisions of this section are not applicable to rosins and rosin derivatives identified in § 175.300(b) (3) (v) of this chapter and used in resinous and polymeric coatings complying with § 175.300 of this chapter.

(e) The provisions of this section are not applicable to rosins and rosin derivatives identified in § 175.105(c) (5) of this chapter and used in defoaming agents complying with § 176.210 of this chapter, food-packaging adhesives complying with § 175.105 of this chapter, and rubber articles complying with § 177.2600 of this chapter.

(f) The analytical methods for determining whether rosins and rosin derivatives conform to the specifications prescribed in paragraph (a) of this section are as follows:

(1) Color: Color shall be determined by ASTM Method D 509–55.

(2) Refractive index: Refractive index shall be determined by ASTM Method D 1747–62.

(3) Acid number: Acid number shall be determined by ASTM Method D 465–59.

(4) Viscosity: Viscosity in poises shall be determined by ASTM Method D 1824–66 and in Saybolt seconds by ASTM Method D 88–56.

(5) Softening point: Softening point shall determined by ASTM Method E 28–67.

(6) Analytical methods for determining drop-softening point, saponification number, and any other specification not listed under paragraph (f) (1) through (5) of this section are available upon request from the Commissioner of Food and Drugs.

§ 178.3900 Sodium pentachlorophenate.

Sodium pentachlorophenate may be safely used as a preservative for ammonium alginate employed as a processing aid in the manufacture of polyvinyl chloride emulsion polymers intended for use as articles or components of articles that contact food at temperatures not to exceed room temperature. The quantity of sodium pentachlorophenate used shall not exceed 0.5 percent by weight of ammonium alginate solids.

§ 178.3910 Surface lubricants used in the manufacture of metallic articles.

The substances listed in this section may be safely used in surface lubricants employed in the manufacture of metallic articles that contact food, subject to the provisions of this section.

(a) The following substances may be used in surface lubricants used in the rolling of metallic foil or sheet stock provided that total residual lubricant remaining on the metallic article in the form in which it contacts food does not exceed 0.015 milligram per square inch of metallic food-contact surface:

(1) Substances identified in paragraph (b) (1) and (2) of this section.

(2) Substances identified in this subparagraph.

List of substances	*Limitations*
Acetate esters derived from synthetic straight chain alcohols (complying with § 172.864 of this chapter) that have even numbers of carbon atoms in the range C_8–C_{18}.	
Tert-Butyl alcohol	
Di(2-ethylhexyl)phthalate	
Diethyl phthalate	
Dimers, trimers, and/or their partial methyl esters; such dimers and trimers are of unsaturated C_{18} fatty acids derived from animal and vegetable fats and oils and/or tall oil, and such partial methyl esters meet the following specifications: Saponification value 187–193, acid value 75–95, and maximum iodine value 15.	For use only at a level not to exceed 10 pct by weight of finished lubricant formulation.
Di-*n*-octyl sebacate	
Ethylenediaminetetraacetic acid, sodium salts.	
Isopropyl alcohol	
Isopropyl oleate	
Methyl esters of coconut oil fatty acids	
Methyl esters of fatty acids (C_{16}–C_{18}) derived from animal and vegetable fats and oils.	
Polybutene, hydrogenated: complying with the identity prescribed under § 178.3740(b).	
Polyethylene glycol (400) monostearate.	
Polyisobutylene (minimum molecular weight 300).	
Polyvinyl alcohol	
Sodium nitrite	For use only as a rust inhibitor in lubricant formulations provided the total residual sodium nitrite on the metallic article in the form in which it contacts food does not exceed 0.007 milligram per square inch of metallic food-contact surface.
Synthetic alcohol mixture of straight- and branched-chain alcohols that have even numbers of carbon atoms in the range C_8–C_{18} and that are prepared from ethylene, aluminum, and hydrogen such that the finished synthetic alcohol mixture contains not less than 75 pct of straight-chain primary alcohols and contains not less than 85 pct total C_{10} and C_{12} alcohols.	
Synthetic primary alcohol mixture of straight- and branched-chain alcohols that contain at least 99 pct primary alcohols consisting of the following: not less than 70 pct normal alcohols; not less than 96.5 pct C_{12}–C_{15} alcohols; and not more than 2.5 pct alpha, omega C_{12}–C_{28} diols. The alcohols are prepared from linear olefins from a purified kerosene fraction, carbon monoxide and hydrogen using a modified oxo process, such that the finished primary alcohol mixture meets the following specifications: Molecular weight, 207±4; hydroxyl number, 263–276.	For use at a level not to exceed 8 pct by weight of the finished lubricant formulation.
Synthetic primary alcohol mixture of straight- and branched-chain alcohols that contain at least 99 pct primary alcohols consisting of the following: not less than 70 percent normal alcohols; not less than 93 pct C_{12}–C_{18} alcohols; not more than 5 pct C_{14}–C_{15} alcohols; and not more than 2.5 pct alpha, omega, C_{12}–C_{28} diols. The alcohols are prepared from linear olefins from a purified kerosene fraction, carbon monoxide and hydrogen using a modified oxo process, such that the finished primary alcohol mixture meets the following specifications: Molecular weight 194±5; hydroxyl number, 283–296.	For use only at a level not to exceed 8 pct by weight of the finished lubricant formulation.
Tallow, sulfonated	
Triethanolamine	

(3) Mineral oil conforming to the identity prescribed in § 178.3620(c).

(4) Light petroleum hydrocarbons identified in paragraph (a) (4) (i) of this section: *Provided*, That the total residual lubricant on the metallic article in the form in which it contacts food meets the ultraviolet absorbance limits prescribed in paragraph (a) (4) (ii) of this section as determined by the analytical method described in paragraph (a) (4) (iii) of this section.

(i) Light petroleum hydrocarbons are derived by distillation from virgin petroleum stocks or are synthesized from petroleum gases. They are chiefly paraffinic, isoparaffinic, naphthenic, or aromatic in nature, and meet the following specifications:

(*a*) Initial boiling point is 75° F minimum and final boiling point is 550° F maximum, as determined by ASTM Method D–86.

(*b*) Nonvolatile residue is 0.005 gram per 100 milliliters, maximum, as determined by ASTM Method D–381 when the final boiling point is 250° F or above and by ASTM Method D–1353 when the final boiling point is below 250° F.

(*c*) Saybolt color 20 minimum as determined by ASTM Method D–156.

(*d*) Aromatic component content shall not exceed 32 percent.

(*e*) Conforms with ultraviolet absorbance limits prescribed in § 178.3620(c) as determined by the analytical method described therein.

(ii) Ultraviolet absorbance limits on residual lubricants are as follows:

Wavelength ($m\mu$):	*Maximum absorbance per 5 centimeters optical path length*
280–289	0.7
290–299	.6
300–359	.4
360–400	.09

(iii) The analytical method for determining ultraviolet absorbance limits on residual lubricants is as follows:

General Instructions

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic matter such as oil, grease, detergent, residues, etc. Examine all glassware including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of oil samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

Apparatus

Separatory funnels. 250-milliliter, 500-milliliter, 1,000-milliliter, and preferably 2,000-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Evaporation flask (optional). 250-milliliter or 500-milliliter capacity all-glass flask equipped with standard-taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of contained liquid to be evaporated.

Spectrophotometric cells. Fused quartz cells, optical path length in the range of 5.000 centimeters ±0.005 centimeter; also for checking spectrophotometer performance only, optical path length in the range 1.000 centimeter ±0.005 centimeter. With distilled water in the cells, determine any absorbance differences.

Spectrophotometer. Special range 250 millicrons-400 millimicrons with spectral slit width of 2 millimicrons or less; under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Absorbance accuracy,[1] ±0.05 at 0.4 absorbance.

Wavelength repeatability, ±0.2 millimicron.

Wavelength accuracy, ±1.0 millimicron.

Soxhlet apparatus. 60-millimeter diameter body tubes fitted with condenser and 500-milliliter round-bottom boiling flask. A supply of paper thimbles to fit is required.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

Reagents and Materials

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane (2,2,4-trimethylpentane) shall pass the following test:

Place 180 milliliters of solvent in a 250-milliliter Erlenmeyer flask, add 1 milliliter of purified *n*-hexadecane and evaporate on the steam bath under a stream of nitrogen (a loose aluminum foil jacket around the flask will speed evaporation). Discontinue evaporation when not over 1 milliliter of residue remains.

Alternatively, the evaporation time can be reduced by using the optional evaporation flask. In this case the solvent and *n*-hexadecane are placed in the flask on the steam bath, the tube assembly is inserted, and a stream of nitrogen is fed through the inlet tube while the outlet tube is connected to a solvent trap and vacuum line in such a way as to prevent any flow-back of condensate into the flask.

Dissolve the 1 milliliter of hexadecane residue in isooctane and make to 25 milliliters volume. Determine the absorbance in the 5-centimeter path length cells compared to isooctane as reference. The absorbance of the solution of the solvent residue shall not exceed 0.01 per centimeter path length between 280 and 400 $m\mu$. Purify, if necessary, by passage through a column of activated silica gel (Grade 12, Davison Chemical Co., Baltimore, Maryland, or equivalent) about 90 centimeters in length and 5 centimeters to 8 centimeters in diameter.

n-Hexadecane, 99-percent olefin-free. Dilute 1.0 milliliter of *n*-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 5-centimeter cell compared to isooctane as reference point between 280 $m\mu$–400 $m\mu$. The absorbance per centimeter path length shall not exceed 0.00 in this range. Purify, if necessary, by percolation through activated silica gel or by distillation.

Dimethyl sulfoxide. Spectrophotometric grade (Crown Zellerbach Corp., Camas, Washington, or equivalent). Absorbance (1-centimeter cell, distilled water reference, sample completely saturated with nitrogen).

Wavelength:	*Absorbance (maximum)*
261.5	1.00
270	.20
275	.09
280	.06
300	.015

[1] As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, 1949. The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons.

There shall be no irregularities in the absorbance curve within these wavelengths.

Phosphoric acid. 85 percent A.C.S. reagent grade.

Sodium sulfate, anhydrous, A.C.S. reagent grade, preferably in granular form. For each bottle of sodium sulfate reagent used, establish as follows the necessary sodium sulfate prewash to provide such filters required in the method: Place approximately 35 grams of anhydrous sodium sulfate in a 30-milliliter coarse, fritted-glass funnel or in a 65-milliliter filter funnel with glass wool plug; wash with successive 15-milliliter portions of the indicated solvent until a 15-milliliter portion of the wash shows 0.00 absorbance per centimeter path length between 280 $m\mu$ and 400 $m\mu$ when tested as prescribed under "Organic solvents." Usually three portions of wash solvent are sufficient.

Before proceeding with analysis of a sample, determine the absorbance in a 5-centimeter path cell between 250 millimicrons and 400 millimicrons for the reagent blank by carrying out the procedure, without a metal sample. The absorbance per centimeter path length should not exceed 0.02 in the wavelength range from 280 $m\mu$ to 400 $m\mu$.

Place 300 milliliters of dimethyl sulfoxide in a 1-liter separatory funnel and add 75 milliliters of phosphoric acid. Mix the contents of the funnel and allow to stand for 10 minutes. (The reaction between the sulfoxide and the acid is exothermic. Release pressure after mixing, then keep funnel stoppered.) Add 150 milliliters of isooctane and shake to preequilibrate the solvents. Draw off the individual layers and store in glass-stoppered flasks.

Procedure

Sample. Select metal foil or sheet stock for the test which has not been previously contaminated by careless handling or exposure to atmospheric dust and fumes. A commercial coil in the form supplied for spindle mounting in a packaging line or wrapping machine is most suitable. Strip off the outside turn of metal and discard. Carefully avoid contamination or damage from handling the metal (wear gloves). Remove a 16-18-foot length from the coil and place it on a flat surface protected by a length of new kraft paper. Cut four 15-foot strips from the sample, each 3 inches wide (avoid tearing the edges of the strips). Using a piece of suitable glass rod, roll the strips of metal into loose coils and insert each into a Soxhlet thimble. Each turn of coil should be visibly separated from the adjacent turn.

Extraction. Fill each of the four Soxhlet tubes with purified isooctane (see under heading "Reagents and Materials," above) until siphon action occurs and then refill the tube body. Supply heat to the boiling flask and allow extraction to continue for at least 8 hours or until repeated weighings of the dried and cooled coil show no further weight loss.

Combine the isooctane extracts from the four Soxhlet units in a suitable beaker, rinsing each tube and flask into the beaker with fresh purified solvent. Evaporate the solvent under an atmosphere of inert gas (nitrogen) to residual volume of 50–60 milliliters and transfer this solution to a 500-milliliter separatory funnel containing 100 milliliters of preequilibrated sulfoxide-phosphoric acid mixture. Complete the transfer of the sample with small portions of preequilibrated isooctane to give a total volume of the residue and solvent of 75 milliliters. Shake the funnel vigorously for 2 minutes. Set up three 250-milliliter separatory funnels with each containing 30 milliliters of preequilibrated isooctane. After separation of liquid phases, carefully draw off lower layer into the first 250-milliliter separatory funnel and wash in tandem with the 30-milliliter portion of iso-

octane contained in the 250-milliliter separatory funnels. Shaking time for each wash is 1 minute. Repeat the extraction operation with two additional portions of the sulfoxide-acid mixture and wash each extractive in tandem through the same three portions of isooctane.

Collect the successive extractives (300 milliliters total) in a separatory funnel (preferably 2-liter) containing 480 milliliters of distilled water; mix, and allow to cool for a few minutes after the last extractive has been added. Add 80 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second separatory funnel (preferably 2-liter) and repeat the extraction with 80 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 80-milliliter extractives three times with 100-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate pre-washed with isooctane (see sodium sulfate under "Reagents and Materials" for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the first separatory funnel with the second 80-milliliter isooctane extractive and pass through the sodium sulfate. Then wash the second and first separatory funnels successively with a 20-milliliter portion of isooctane and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of γ-hexadecane and evaporate the isooctane on the steam bath under nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10-milliliter portion of isooctane, reevaporate to 1 milliliter of hexadecane, and repeat this operation once.

Quantitatively transfer the residue with isooctane to a 25-milliliter volumetric flask, make to volume, and mix. Determine the absorbance of the solution in 5-centimeter pathlength cells compared to isooctane as reference between 280mμ–400mμ (take care to lose none of the solution in filling the sample cell). Correct the absorbance values for any absorbance derived from reagents as determined by carrying out the procedure without a metal sample. If the corrected absorbance does not exceed the limits prescribed in this paragraph, the residue meets the ultraviolet absorbance specifications.

(b) The following substances may be used in surface lubricants used to facilitate the drawing, sampling, or forming of metallic articles from rolled foil or sheet stock by further processing provided that the total residual lubricant remaining on the metallic article in the form in which it contacts food does not exceed 0.2 milligram per square inch of food-contact surface:

(1) Antioxidants used in compliance with regulations in Parts 170 through 189 of this chapter.

(2) Substances identified in this subparagraph.

List of substances	*Limitations*
Acetyl tributyl citrate	
Acetyl triethyl citrate	
Butyl stearate	
Castor oil	
Dibutyl sebacate	
Di(2-ethylhexyl) azelate	
Di(2-ethylhexyl) sebacate	
Diisodecyl phthalate	
Dimethylpolysiloxane	Conforming to the identity prescribed in § 181.28 of this chapter.
Dipropylene glycol	
Epoxidized soybean oil	Conforming to the identity prescribed in § 181.27 of this chapter.
Fatty acids derived from animal and vegetable fats and oils, and salts of such acids, single or mixed, as follows:	
Aluminum	
Magnesium	
Potassium	
Sodium	
Zinc	
Fatty alcohols, straight-chain with even number carbon atoms (C_{10} or greater).	
Isobutyl stearate	
Lanolin	
Linoleic acid amide	
Mineral oil	Conforming to the identity prescribed in § 178.3620 (a) or (b).
Mono-, di-, and tristearyl citrate	
Oleic acid amide	
Palmitic acid amide	
Petrolatum	Conforming to the identity prescribed in § 178.3700.
Polyethylene glycol (molecular weight 200 or greater).	Mono- and diethylene glycol content not to exceed a total of 0.2 pct.
Stannous stearate	
Stearic acid amide	
Stearyl stearate	
Triethylene glycol	Diethylene glycol content not to exceed 0.1 pct.
Wax, petroleum	Complying with § 178.3710.

(c) The substances identified in paragraph (a)(2) of this section may be used in surface lubricants used to facilitate the drawing, stamping, and forming of metallic articles from rolled foil and sheet stock provided that total residual lubricant remaining on the metallic article in the form in which it contacts food does not exceed 0.015 milligram per square inch of food-contact surface.

(d) Subject to any prescribed limitations, the quantity of surface lubricant used in the manufacture of metallic articles shall not exceed the least amount reasonably required to accomplish the intended technical effect and shall not be intended to nor, in fact, accomplish any technical effect in the food itself.

(e) The use of the surface lubricants in the manufacture of any article that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter must comply with any specifications prescribed by such regulation for the finished form of the article.

(f) Any substance that is listed in this section and the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter shall comply with any applicable specifications prescribed by such regulation.

§ 178.3930 Terpene resins.

The terpene resins identified in paragraph (a) of this section may be safely used as components of polypropylene film intended for use in contact with food, and the terpene resins identified in paragraph (b) of this section may be safely used as components of polyolefin film intended for use in contact with food;

(a) Terpene resins consisting of the hydrogenated polymers of terpene hydrocarbons obtainable from sulfate turpentine and meeting the following specifications: Drop-softening point of 118°–138° C; iodine value less than 20.

(b) Terpene resins consisting of polymers of beta-pinene and meeting the following specifications: Acid value less than 1; saponification number less than 1; color less than 4 on the Gardner scale as measured in 50 percent mineral spirits solution.

§ 178.3940 Tetraethylene glycol di-(2-ethylhexoate).

Tetraethylene glycol di-(2-ethylhexoate) containing not more than 22 parts per million ethylene and/or diethylene glycols may be used at a level not to exceed 0.7 percent by weight of twine as a finish on twine to be used for tying meat provided the twine fibers are produced from nylon resins complying with § 177.1500 of this chapter.

§ 178.3950 Tetrahydrofuran.

Tetrahydrofuran may be safely used in the fabrication of articles intended for packaging, transporting, or storing foods, subject to the provisions of this section.

(a) It is used as a solvent in the casting of film from a solution of polymeric resins of vinyl chloride, vinyl acetate, or vinylidene chloride that have been polymerized singly or copolymerized with one another in any combination, or it may be used as a solvent in the casting of film prepared from vinyl chloride copolymers complying with § 177.1980 of this chapter.

(b) The residual amount of tetrahydrofuran in the film does not exceed 1.5 percent by weight of film.

§ 178.3970 Ultramarine blue.

Ultramarine blue may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) It is used as a colorant in the manufacture of the following articles:

(1) Flexible, semirigid, and rigid plastic materials.

(2) Textiles and textile fibers as provided in § 177.2800 of this chapter.

(b) The quantity used shall not exceed the amount reasonably required to accomplish the intended effect.

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

Subpart A—[Reserved]

Subpart B—Radiation and Radiation Sources

Sec.
179.21 Sources of radiation used for inspection of food, for inspection of packaged food, and for controlling food processing.
179.22 Low-dose gamma radiation for the treatment of food.
179.24 Low-dose electron beam radiation for the treatment of food.
179.30 Radiofrequency radiation for the heating of food, including microwave frequencies.
179.39 Ultraviolet radiation for the processing and treatment of food.

Subpart C—Packaging Materials for Irradiated Foods

179.45 Packaging materials for use during the irradiation of prepackaged foods.

AUTHORITY: Secs. 409, 701, 52 Stat. 1055–1056 as amended, 72 Stat. 1785–1786 as amended (21 U.S.C. 348, 371), unless otherwise noted.

Subpart A—[Reserved]

Subpart B—Radiation and Radiation Sources

§ 179.21 Sources of radiation used for inspection of food, for inspection of packaged food, and for controlling food processing.

Sources of radiation for the purposes of inspection of foods, for inspection of packaged food, and for controlling food processing may be safely used under the following conditions:

(a) The radiation source is one of the following:

(1) X-ray tubes producing X-radiation from operation of the tube source at energy levels of 300 kilovolt peak or lower.

(2) Sealed units producing radiations at energy levels of not more than 2.2 million electron volts from one of the following isotopes: Americium-241, cesium-137, cobalt-60, iodine-125, krypton-85, radium-226, and strontium-90.

(b) To assure safe use of these radiation sources:

(1) The label of the sources shall bear, in addition to the other information required by the Act:

(i) Appropriate and accurate information identifying the source of radiation.

(ii) The maximum energy of radiation emitted by X-ray tube sources.

(2) The label or accompanying labeling shall bear:

(i) Adequate directions for installation and use.

(ii) A statement that no food shall be exposed to a radiation source so as to receive an absorbed dose in excess of 1000 rads.

§ 179.22 Low-dose gamma radiation for the treatment of food.

Gamma radiation for the treatment of certain foods may be safely used under the following conditions:

(a) The radiation source consists of sealed units containing the isotope cobalt-60 or cesium-137.

(b) The gamma radiation is used or intended for use in a single treatment as follows:

Food for irradiation	Limitations	Use
Wheat	Absorbed dose: 20,000 to 50,000 rd	Control of insect infestation.
Wheat flour from unirradiated wheat	do	Do.
White potatoes	Absorbed dose: 5,000 to 15,000 rd	Inhibit sprout development.

(c) To assure safe use, the label and labeling of the food shall bear, in addition to the other information required by the act, the following statements:

(1) "Treated with ionizing radiation" or "Treated with gamma radiation" on retail packages.

(2) "Treated with ionizing radiation—do not irradiate again" or "Treated with gamma radiation—do not irradiate again" on wholesale packages and on invoices or bills of lading of bulk shipments.

§ 179.24 Low-dose electron beam radiation for the treatment of food.

Electron beam radiation for the treatment of food may be safely used under the following conditions:

(a) The radiation source consists of an electron accelerator producing a beam of electrons at energy levels not to exceed 5 million electron volts.

(b) The electron beam radiation is used or intended for use in a single treatment as follows:

Food for radiation	Limitation	Use
Wheat	Absorbed dose: 20,000 to 50,000 rads. Maximum thickness of food under irradiation: 0.6 cm/Mev of electron energy under single beam irradiation or 1.4 cm/Mev of electron energy with crossfiring beams. Maximum flow: 10 tons per hour per kilowatt under single beam irradiation, or 14 tons per hour per kilowatt with crossfiring beams.	Control of insect infestation.
Wheat flour from unirradiated wheat	do	Do.

(c) In the case of electron beam radiation used for treatment of food, a permanent record of the radiation intensity and power used in the processing shall be made with recorders coupled to the electron accelerator, and the records shall be retained for Food and Drug Administration inspection for a period of 1 year. Such records shall provide information identifying completely the food that has been subjected to the radiation recorded thereon.

(d) To assure safe use, the label and labeling of the food shall bear, in addition to the other information required by the act, the following statements:

(1) "Treated with ionizing radiation" or "Treated with electron radiation" on retail packages.

(2) "Treated with ionizing radiation—do not irradiate again" or "Treated with electron radiation—do not irradiate again" on wholesale packages and on invoices or bills of lading of bulk shipments.

§ 179.30 Radiofrequency radiation for the heating of food, including microwave frequencies.

Radiofrequency radiation, including microwave frequencies, may be safely used for heating food under the following conditions:

(a) The radiation source consists of electronic equipment producing radio waves with specific frequencies for this purpose authorized by the Federal Communications Commission.

(b) The radiation is used or intended for use in the production of heat in food wherever heat is necessary and effective in the treatment or processing of food.

§ 179.39 Ultraviolet radiation for the processing and treatment of food.

Ultraviolet radiation for the processing and treatment of food may be safely used under the following conditions:

(a) The radiation sources consist of ultraviolet emission tubes designed to emit wavelengths within the range of 2200–3000 Angstrom units with 90 percent of the emission being the wavelength 2537 Angstrom units.

(b) The ultraviolet radiation is used or intended for use as follows:

Irradiated food	Limitations	Use
Food and food products	Irradiated with 2,200 to 3,000 A emissions, without ozone production: high fat-content food irradiated in vacuum or in an inert atmosphere; intensity of radiation, 1 W (of 2,537 A radiation) per 5 to 10 ft^2.	Surface microorganism control.
Potable water	Irradiated with 2,200 to 3,000 A emissions, without ozone production; coefficient of absorption, 0.19 per cm. or less; flow rate, 100 gal/h per watt of 2,537 A radiation; water depth, 1 cm or less; lamp-operating temperature, 36° to 46° C.	Sterilization of water used in food production.

Subpart C—Packaging Materials for Irradiated Foods

§ 179.45 Packaging materials for use during the irradiation of prepackaged foods.

The packaging materials identified in this section may be safely subjected to irradiation incidental to the radiation treatment and processing of prepackaged foods, subject to the provisions of this section and to the requirement that no induced radioactivity is detectable in the packaging material itself:

(a) The radiation of the food itself shall comply with regulations in this part.

(b) The following packaging materials may be subjected to a dose of radiation, not to exceed 1 megarad, unless otherwise indicated, incidental to the use of gamma radiation in the radiation treatment of prepackaged foods:

(1) Nitrocellulose-coated or vinylidene chloride copolymer-coated cellophane complying with § 177.1200 of this chapter.

(2) Glassine paper complying with § 176.170 of this chapter.

(3) Wax-coated paperboard complying with § 176.170 of this chapter.

(4) Polyolefin film prepared from one or more of the basic olefin polymers complying with § 177.1520 of this chapter. The finished film may contain:

(i) Adjuvant substances used in compliance with §§ 178.3740 and 181.22 through 181.30 of this chapter, sodium citrate, sodium lauryl sulfate, polyvinyl chloride, and materials as listed in paragraph (c) (2) (i) of this section.

(ii) Coatings comprising a vinylidene chloride copolymer containing a minimum of 85 percent vinylidene chloride with one or more of the following comonomers: Acrylic acid, acrylonitrile, itaconic acid, methyl acrylate, and methyl methacrylate.

(5) Kraft paper prepared from unbleached sulfate pulp to which rosin, complying with § 178.3870 of this chapter, and alum may be added. The kraft paper is used only as a container for flour and is irradiated with a dose not exceeding 50,000 rads.

(6) Polyethylene terephthalate film prepared from the basic polymer as described in § 177.1630(d) (4) (i) of this chapter. The finished film may contain:

(i) Adjuvant substances used in compliance with §§ 178.3740 and 181.22 through 181.30 of this chapter, sodium citrate, sodium lauryl sulfate, polyvinyl chloride, and materials as listed in paragraph (c) (2) (i) of this section.

(ii) Coatings comprising a vinylidene chloride copolymer containing a minimum of 85 percent vinylidene chloride with one or more of the following comonomers: Acrylic acid, acrylonitrile, itaconic acid, methyl acrylate, and methyl methacrylate.

(iii) Coatings consisting of polyethylene comforming to § 177.1520 of this chapter.

(7) Polystyrene film prepared from styrene basic polymer. The finished film may contain adjuvant substances used in compliance with §§ 178.3740 and 181.22 through 181.30 of this chapter.

(8) Rubber hydrochloride film prepared from rubber hydrochloride basic polymer having a chlorine content of 30–32 weight percent and having a maximum extractable fraction of 2 weight percent when extracted with *n*-hexane at reflux temperature for 2 hours. The finished film may contain adjuvant substances used in compliance with §§ 178.3740 and 181.22 through 181.30 of this chapter.

(9) Vinylidene chloride-vinyl chloride copolymer film prepared from vinylidene chloride-vinyl chloride basic copolymers containing not less than 70 weight percent of vinylidene chloride and having a viscosity of 0.50–1.50 centipoises as determined by ASTM method D 729–57. The finished film may contain adjuvant substances used in compliance with §§ 178.3740 and 181.22 through 181.30 of this chapter.

(10) Nylon 11 conforming to § 177.1500 of this chapter.

(c) The following packaging materials may be subjected to a dose of radiation, not to exceed 6 megarads incidental to the use of gamma or X-radiation in the radiation processing of prepackaged foods:

(1) Vegetable parchments, consisting of a cellulose material made from waterleaf paper (unsized) treated with concentrated sulfuric acid, neutralized, and thoroughly washed with distilled water.

(2) Films prepared from basic polymers and with or without adjuvants, as follows:

(i) Polyethylene film prepared from the basic polymer as described in § 177.1520(a) of this chapter. The finished film may contain one of more of the following added substances:

Substances	*Limitations*
Amides of erucic, linoleic, oleic, palmitic, and stearic acid.	Not to exceed 1 pct by weight of the polymer.
BHA as described in § 172.110 of this chapter.	Do.
BHT as described in § 172.115 of this chapter.	Do.
Calcium and sodium propionates	Do.
Petroleum wax as described in § 178.3710 of this chapter.	Do.
Polypropylene, noncrystalline, as described in § 177.1520(c) of this chapter.	Not to exceed 2 pct by weight of the polymer.
Stearates of aluminum, calcium, magnesium, potassium, and sodium as described in § 172.863(a) of this chapter.	Not to exceed 1 pct by weight of the polymer.
Triethylene glycol as described in § 178.3740(b) of this chapter.	Do.
Mineral oil as described in § 178.3620 (a) or (b) of this chapter.	Do.

(ii) Polyethylene terephthalate film prepared from the basic polymer as described in § 177.1630(d) (4) (i) of this chapter. The finished film may contain one or more of the added substances listed in subdivision (i) of this subparagraph.

(iii) Nylon 6 films prepared from the nylon 6 basic polymer as described in § 177.1500(a) (6) of this chapter and meeting the specifications of item 6.1 of the table in § 177.1500(b) of this chapter. The finished film may contain one or more of the added substances listed in paragraph (c) (2) (i) of this section.

(iv) Vinyl chloride-vinyl acetate copolymer film prepared from the basic copolymer containing 88.5 to 90.0 weight percent of vinyl chloride with 10.0 to 11.5 weight percent of vinyl acetate and having a maximum volatility of not over 3.0 percent (1 hour at 105° C) and viscosity not less than 0.30 determined by ASTM D–1243–60, Method A. The finished film may contain one or more of the added substances listed in paragraph (c) (2) (i) of this section.

(d) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

PART 180—FOOD ADDITIVES PERMITTED IN FOOD ON AN INTERIM BASIS OR IN CONTACT WITH FOOD PENDING ADDITIONAL STUDY

Subpart A—General Provisions

Sec.
180.1 General.

Subpart B—Specific Requirements for Certain Food Additives

Sec.
180.22 Acrylonitrile copolymers.
180.25 Mannitol.
180.30 Brominated vegetable oil.
180.37 Saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin.

AUTHORITY: Secs. 409, 701, 52 Stat. 1055–1056 as amended, 72 Stat. 1785–1788 as amended (21 U.S.C. 348, 371), unless otherwise noted.

Subpart A—General Provisions

§ 180.1 General.

(a) Substances having a history of use in food for human consumption or in food contact surfaces may at any time have their safety or functionality brought into question by new information that in itself is not conclusive. An interim food additive regulation for the use of any such substance may be promulgated in this subpart when new information raises a substantial question about the safety or functionality of the substance but there is a reasonable certainty that the substance is not harmful and that no harm to the public health will result from the continued use of the substance for a limited period of time while the question raised is being resolved by further study.

(b) No interim food additive regulation may be promulgated if the new information is conclusive with respect to the question raised or if there is a reasonable likelihood that the substance is harmful or that continued use of the

substance will result in harm to the public health.

(c) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to Part 2 of this chapter, may propose an interim food additive regulation. A final order promulgating an interim food additive regulation shall provide that continued use of the substance in food is subject to each of the following conditions:

(1) Use of the substance in food or food contact surfaces must comply with whatever limitations the Commissioner deems to be appropriate under the circumstances.

(2) Within 60 days following the effective date of the regulation, an interested person shall satisfy the Commissioner in writing that studies adequate and appropriate to resolve the questions raised about the substance have been undertaken, or the Food and Drug Administration may undertake the studies. The Commissioner may extend this 60-day period if necessary to review and act on proposed protocols. If no such commitment is made, or adequate and appropriate studies are not undertaken, an order shall immediately be published in the FEDERAL REGISTER revoking the interim food additive regulation effective upon publication.

(3) A progress report shall be filed on the studies every January 1 and July 1 until completion. If the progress report is inadequate or if the Commissioner concludes that the studies are not being pursued promptly and diligently or if interim results indicate a reasonable likelihood that a health hazard exists, an order will promptly be published in the FEDERAL REGISTER revoking the interim food additive regulation effective upon publication.

(d) Promptly upon completion of the studies undertaken on the substance, the Commissioner will review all available data, will terminate the interim food additive regulation, and will either issue a food additive regulation or will require elimination of the substance from the food supply.

(e) The Commissioner may consult with advisory committees, professional organizations, or other experts in the field, in evaluating:

(1) Whether an interim food additive regulation is justified,

(2) The type of studies necessary and appropriate to resolve questions raised about a substance,

(3) Whether interim results indicate the reasonable likelihood that a health hazard exists, or

(4) Whether the data available at the conclusion of those studies justify a food additive regulation.

Subpart B—Specific Requirements for Certain Food Additives

§ 180.22 Acrylonitrile copolymers.

Acrylonitrile copolymers may be safely used on an interim basis as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) Limitations for acrylonitrile monomer extraction for finished food-contact articles, determined by using methods of analysis available upon request from the Food and Drug Administration, Bureau of Foods, Division of Food and Color Additives, 200 C St. SW., Washington, DC 20204, are as follows:

(1) In the case of single-use articles having a volume to surface ratio of 10 milliliters or more per square inch of food contact surface—0.003 milligram/square inch when extracted to equilibrium at 120° F with food-simulating solvents appropriate to the intended conditions of use.

(2) In the case of single-use articles having a volume to surface ratio of less than 10 milliliters per square inch of food contact surface—0.3 part per million calculated on the basis of the volume of the container when extracted to equilibrium at 120° F with food-simulating solvents appropriate to the intended conditions of use.

(3) In the case of repeated-use articles—0.003 milligram/square inch when extracted at a time equivalent to initial batch usage utilizing food-simulating solvents and temperatures appropriate to the intended conditions of use.

The food-simulating solvents shall include, where applicable, distilled water, 8 percent or 50 percent ethanol, 3 percent acetic acid, and either *n*-heptane or an appropriate oil or fat.

(b) Where necessary, current regulations permitting the use of acrylonitrile copolymers shall be revised to specify limitations on acrylonitrile/mercaptan complexes utilized in the production of acrylonitrile copolymers. Such copolymers, if they contain reversible acrylonitrile/mercaptan complexes and are used in other than repeated-use conditions, shall be tested to determine the identity of the complex and the level of the complex present in the food-contact article. Such testing shall include determination of the rate of decomposition of the complex at temperatures of 100° F, 160° F, and 212° F using 3 percent acetic acid as the hydrolic agent. Acrylonitrile monomer levels, acrylonitrile/mercaptan complex levels, acrylonitrile oligomer levels, descriptions of the analytical methods used to determine the complex and the acrylonitrile migration, and validation studies of these analytical methods shall be submitted by June 9, 1977, to the Food and Drug Administration, Bureau of Foods, Division of Food and Color Additives, 200 C St. SW., Washington, D.C. 20204, unless an extension is granted by the Food and Drug Administration for good cause shown. Analytical methods for the determination of acrylonitrile complexes with *n*-dodecylmercaptan, *n*-octyl mercaptan, and 2-mercaptoethanol are available upon request from the Division of Food and Color Additives.

(c) The following data shall be provided for finished food-contact articles intended for repeated use:

(1) Qualitative and quantitative migration values at a time equivalent to initial batch usage, utilizing solvents and temperatures appropriate to the intended conditions of use.

(2) Qualitative and quantitative migration values at the time of equilibrium extractions, utilizing solvents and temperatures appropriate to the intended conditions of use.

(3) Data on the volume and/or weight of food handled during the initial batch time period(s), during the equilibrium test period, and over the estimated life of the food-contact surface.

(d) Where acrylonitrile copolymers represent only a minor component of a polymer system, calculations based on 100 percent migration of the acrylonitrile component may be submitted in lieu of the requirements of paragraphs (a), (b), and (c) of this section in support of the continued safe use of acrylonitrile copolymers.

(e) On or before September 13, 1976, any interested person shall satisfy the Commissioner of Food and Drugs that toxicological feeding studies adequate and appropriate to establish safe conditions for the use of acrylonitrile copolymers have been, or soon will be, undertaken. Toxicity studies of acrylonitrile monomer shall include (1) lifetime feeding studies with a mammalian species, preferably with animals exposed in utero to the chemical, (2) studies of multigeneration reproduction with oral administration of the test material, (3) assessment of teratogenic and mutagenic potentials, (4) subchronic oral administration in a nonrodent mammal, (5) tests to determine any synergistic toxic effects between acrylonitrile monomer and cyanide ion, and (6) a literature search on the effects of chronic ingestion of hydrogen cyanide. Data on levels of acrylamide extractable from acrylonitrile copolymers shall also be submitted. Protocols of testing should be submitted for review to the Food and Drug Administration, Bureau of Foods, Division of Food and Color Additives (HFF–330), 200 C St. SW., Washington, D.C. 20204.

(f) Acrylonitrile copolymers may be used in contact with food only if authorized in Parts 174 through 179 or § 181.32 of this chapter except that other uses of acrylonitrile copolymers in use prior to June 14, 1976, may continue under the following conditions:

(1) On or before August 13, 1976, each use of acrylonitrile copolymers in a manner not authorized by § 181.32 of this chapter or Parts 174 through 179 of this chapter shall be the subject of a notice to the Food and Drug Administration, Bureau of Foods, Division of Food and Color Additives (HFF–330), 200 C St. SW., Washington, DC 20204. Such notice shall be accompanied by a statement of the basis, including any articles and correspondence, on which the user in good faith believed the use to be prior-sanctioned. The Commissioner of Food and Drugs shall, by notice in the FEDERAL REGISTER, identify any use of acrylonitrile copolymers not in accordance with this paragraph. Those uses are thereafter unapproved food additives and consequently unlawful.

(2) Any use of acrylonitrile copolymers subject to paragraph (f)(1) of this section shall be the subject of a petition submitted on or before December 13, 1976, in accordance with § 171.1 of this chapter, unless an extension of time is granted by the Food and Drug Administration for good cause shown. Any application for extension shall be by petition submitted in accordance with the requirements of Part 2 of this chapter. If a petition is denied, in whole or in part, those uses subject to the denial are thereafter unapproved food additives and consequently unlawful.

(3) Any use of acrylonitrile copolymers subject to paragraph (f)(1) of this section shall meet the acrylonitrile monomer extraction limitation set forth in paragraph (a) of this section and shall be subject to the requirements of paragraph (b) of this section.

(g) In addition to the requirements of this section, the use of acrylonitrile copolymers shall comply with all applicable requirements in other regulations in this part.

§ 180.25 Mannitol.

(a) Mannitol is the chemical 1,2,3,4,5,6,-hexanehexol ($C_6H_{14}O_6$) a hexahydric alcohol, differing from sorbitol principally by having a different optical rotation. Mannitol is produced by the electrolytic reduction, or the transition metal catalytic hydrogenation, of sugar solutions containing glucose or fructose.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).[11]

(c) The ingredient is used as an anticaking agent and free-flow agent as defined in § 170.3(o)(1) of this chapter, formulation aid as defined in § 170.3(o)(14) of this chapter, firming agent as defined in § 170.3(o)(10) of this chapter, flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter, lubricant and release agent as defined in § 170.3(o)(18) of this chapter, nutritive sweetener as defined in § 170.3(o)(21) of this chapter, processing aid as defined in § 170.3(o)(24) of this chapter, stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, surface-finishing agent as defined in § 170.3(o)(30) of this chapter, and texturizer as defined in § 170.3(o)(32) of this chapter.

(d) The ingredient is used in food at levels not to exceed 98 percent in pressed mints and 5 percent in all other hard candy and cough drops as defined in § 170.3(n)(25) of this chapter, 31 percent in chewing gum as defined in § 170.3(n)(6) of this chapter, 40 percent in soft candy as defined in § 170.3(n)(38) of this chapter, 8 percent in confections and frostings as defined in § 170.3(n)(9) of this chapter, 15 percent in nonstandardized jams and jellies, commercial, as defined in § 170.3(n)(28) of this chapter, and at levels less than 2.5 percent in all other foods.

[11] Copies may be obtained from: The National Academy of Sciences, 2101 Constitution Ave. NW., Washington, D.C. 20037.

(e) The label and labeling of food whose reasonably foreseeable consumption may result in a daily ingestion of 20 grams of mannitol shall bear the statement "Excess consumption may have a laxative effect".

(f) In accordance with § 180.1, adequate and appropriate feeding studies have been undertaken for this substance. Continued uses of this ingredient are contingent upon timely and adequate progress reports of such tests, and no indication of increased risk to public health during the test period.

(g) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

§ 180.30 Brominated vegetable oil.

The food additive brominated vegetable oil may be safely used in accordance with the following prescribed conditions:

(a) The additive complies with specifications prescribed in Food Chemicals Codex, First Edition, except that free fatty acids (as oleic) shall not exceed 2.5 percent and iodine value shall not exceed 16.

(b) The additive is used on an interim basis as a stabilizer for flavoring oils used in fruit-flavored beverages, for which any applicable standards of identity do not preclude such use, in an amount not to exceed 15 parts per million in the finished beverage, pending the outcome of additional toxicological studies on which periodic reports at 6-month intervals are to be furnished and final results submitted to the Food and Drug Administration promptly after completion of the studies.

§ 180.37 Saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin.

The food additives saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin may be safely used as sweetening agents in food in accordance with the following conditions, if the substitution for nutritive sweeteners is for a valid special dietary purpose and is in accord with current special dietary food regulations and policies or if the use or intended use is for an authorized technological purpose other than calorie reduction:

(a) Saccharin is the chemical, 1,2-benzisothiazolin-3-one-1,1-dioxide ($C_7H_5NO_3S$). The named salts of saccharin are produced by the additional neutralization of saccharin with the proper base to yield the desired salt.

(b) The food additives meet the specifications of the "Food Chemicals Codex."

(c) Authority for such use shall expire when the Commissioner receives the final reports on the ongoing studies in Canada and publishes an order on the safety of saccharin and its salts based on those reports and other available data.

(d) The additives are used or intended for use as a sweetening agent only in special dietary foods, as follows:

(1) In beverages, fruit juice drinks, and bases or mixes when prepared for consumption in accordance with directions, in amounts not to exceed 12 milligrams of the additive, calculated as saccharin, per fluid ounce.

(2) As a sugar substitute for cooking or table use, in amounts not to exceed 20 milligrams of the additive, calculated as saccharin, for each expressed teaspoonful of sugar sweetening equivalency.

(3) In processed foods, in amounts not to exceed 30 milligrams of the additive, calculated as saccharin, per serving of designated size.

(e) The additives are used or intended for use only for the following technological purposes:

(1) To reduce bulk and enhance flavors in chewable vitamin tablets, chewable mineral tablets, or combinations thereof.

(2) To retain flavor and physical properties of chewing gum.

(3) To enhance flavor of flavor chips used in nonstandardized bakery products.

(f) To assure safe use of the additives, in addition to the other information required by the act:

(1) The label of the additive and any intermediate mixes of the additive for manufacturing purposes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration of the additive, expressed as saccharin, in any intermediate mix.

(iii) Adequate directions for use to provide a final food product that complies with the limitations prescribed in paragraphs (d) and (e) of this section.

(2) The label of any finished food product containing the additive shall bear:

(i) The name of the additive.

(ii) The amount of the additive, calculated as saccharin, as follows:

(*a*) For beverages, in milligrams per fluid ounce;

(*b*) For cooking or table use products, in milligrams per dispensing unit;

(*c*) For processed foods, in terms of the weight or size of a serving which shall be that quantity of the food containing 30 milligrams or less of the additive.

(iii) When the additive is used for calorie reduction, such other labeling as is required by Part 105 or § 100.130 of this chapter.

PART 181—PRIOR-SANCTIONED FOOD INGREDIENTS

Subpart A—General Provisions

Sec.
181.1 General.
181.5 Prior sanctions.

Subpart B—Specific Prior-Sanctioned Food Ingredients

181.22 Certain substances employed in the manufacture of food-packaging materials.
181.23 Antimycotics.
181.24 Antioxidants.
181.25 Driers.

Sec.
181.26 Drying oils as components of finished resins.
181.27 Plasticizers.
181.28 Release agents.
181.29 Stabilizers.
181.30 Substances used in the manufacture of paper and paperboard products used in food packaging.
181.32 Acrylonitrile polymers and resins.

AUTHORITY: Secs. 409, 701, 52 Stat. 1055–1056 as amended, 72 Stat. 1785–1788 as amended (21 U.S.C. 348, 371), unless otherwise noted.

Subpart A—General Provisions

§ 181.1 General.

(a) An ingredient whose use in food or food packaging is subject to a prior sanction or approval within the meaning of section 201(s)(4) of the act is exempt from classification as a food additive. The Commissioner will publish in this part all known prior sanctions. Any interested person may submit to the Commissioner a request for publication of a prior sanction, supported by evidence to show that it falls within section 201(s)(4) of the act.

(b) Based upon scientific data or information that shows that use of a prior-sanctioned food ingredient may be injurious to health, and thus in violation of section 402 of the act, the Commissioner will establish or amend an applicable prior sanction regulation to impose whatever limitations or conditions are necessary for the safe use of the ingredient, or to prohibit use of the ingredient.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055 and 72 Stat. 1784–1788, as amended (21 U.S.C. 321(s), 348, 371(a)).)

§ 181.5 Prior sanctions.

(a) A prior sanction shall exist only for a specific use(s) of a substance in food, i.e., the level(s), condition(s), product(s), etc., for which there was explicit approval by the Food and Drug Administration or the United States Department of Agriculture prior to September 6, 1958.

(b) The existence of a prior sanction exempts the sanctioned use(s) from the food additive provisions of the act but not from the other adulteration or the misbranding provisions of the act.

(c) All known prior sanctions shall be the subject of a regulation published in this part. Any such regulation is subject to amendment to impose whatever limitation(s) or condition(s) may be necessary for the safe use of the ingredient, or revocation to prohibit use of the ingredient, in order to prevent the adulteration of food in violation of section 402 of the act.

(d) In proposing, after a general evaluation of use of an ingredient, regulations affirming the GRAS status of substances added directly to human food in Part 184 of this chapter or substances in food-contact surfaces in Part 186 of this chapter, or establishing a food additive regulation for substances added directly to human food in Parts 172 and 173 of this chapter or food additives in food-contact surfaces in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, the Commissioner shall, if he is aware of any prior sanction for use of the ingredient under conditions different from those proposed in the regulation, concurrently propose a separate regulation covering such use of the ingredient under this part. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any food additive or GRAS regulation promulgated after a general evaluation of use of an ingredient constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to a proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under this part, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

Subpart B—Specific Prior-Sanctioned Food Ingredients

§ 181.22 Certain substances employed in the manufacture of food-packaging materials.

Prior to the enactment of the food additives amendment to the Federal Food, Drug, and Cosmetic Act, sanctions were granted for the usage of the following substances in the manufacture of packaging materials. So used, these substances are not considered "food additives" within the meaning of section 201(s) of the act, provided that they are of good commercial grade, are suitable for association with food, and are used in accordance with good manufacturing practice. For the purpose of this section, good manufacturing practice for food-packaging materials includes the restriction that the quantity of any of these substances which becomes a component of food as a result of use in food-packaging materials shall not be intended to accomplish any physical or technical effect in the food itself, shall be reduced to the least amount reasonably possible, and shall not exceed any limit specified in this subpart.

§ 181.24 Antioxidants.

Substances classified as antioxidants, when added to food (limit of addition to food, 0.005 percent) shall include:

Butylated hydroxyanisole.
Butylated hydroxytoluene.
Dilauryl thiodipropionate.
Distearyl thiodipropionate.
Gum guaiac.
Nordihydroguaiaretic acid.
Propyl gallate.
Thiodipropionic acid.
2,4,5-Trihydroxy butyrophenone.

§ 181.23 Antimycotics.

Substances classified as antimycotics, when added to food shall include:

Calcium propionate.
Methylparaben (methyl *p*-hydroxybenzoate).
Propylparaben (propyl *p*-hydroxybenzoate).
Sodium benzoate.
Sodium propionate.
Sorbic acid.

§ 181.25 Driers

Substances classified as driers, when added to food, shall include:

Cobalt caprylate.
Cobalt linoleate.
Cobalt naphthenate.
Cobalt tallate.
Iron caprylate.
Iron linoleate.
Iron naphthenate.
Iron tallate.
Manganese caprylate.
Manganese linoleate.
Manganese naphthenate.
Manganese tallate.

§ 181.26 Drying oils as components of finished resins.

Substances classified as drying oils, when added to food (as components of finished resins) shall include:

Chinawood oil (tung oil).
Dehydrated castor oil.
Linseed oil.
Tall oil.

§ 181.27 Plasticizers.

Substances classified as plasticizers, when added to food, shall include:

Acetyl tributyl citrate.
Acetyl triethyl citrate.
p-tert-Butylphenyl salicylate.
Butyl stearate.
Butylphthalyl butyl glycolate.
Dibutyl sebacate.
Di-(2-ethylhexyl) phthalate (for foods of high water content only).
Diethyl phthalate.
Diisobutyl adipate.
Diisooctyl phthalate (for foods of high water content only).
Diphenyl-2-ethylhexyl phosphate.
Epoxidized soybean oil (iodine number maximum 6; and oxirane oxygen, minimum, 6.0 percent).
Ethylphthalyl ethyl glycolate.
Glycerol monooleate.
Monoisopropyl citrate.
Mono, di-, and tristearyl citrate.
Triacetin (glycerol triacetate).
Triethyl citrate.
3-(2-Xenoyl)-1,2-epoxypropane.

§ 181.28 Release agents.

Substances classified as release agents, when added to food, shall include:

Dimethylpolysiloxane (substantially free from hydrolyzable chloride and alkoxy groups, no more than 13 percent loss in weight after heating 4 hours at 200° C.; viscosity 300 centistokes, 600 centistokes at 25° C, specific gravity 0.96 to 0.97 at 25° C, refractive index 1.400 to 1.404 at 25° C).
Linoleamide (linoleic acid amide).
Oleamide (oleic acid amide).
Palmitamide (palmitic acid amide).
Stearamide (stearic acid amide).

§ 181.29 Stabilizers.

Substances classified as stabilizers, when added to food, shall include:

Aluminum mono-, di-, and tristearate.
Ammonium citrate.
Ammonium potassium hydrogen phosphate.
Calcium glycerophosphate.
Calcium phosphate.
Calcium hydrogen phosphate.

Calcium oleate.
Calcium acetate.
Calcium carbonate.
Calcium ricinoleate.
Calcium stearate.
Disodium hydrogen phosphate.
Magnesium glycerophosphate.
Magnesium stearate.
Magnesium phosphate.
Magnesium hydrogen phosphate.
Mono-, di-, and trisodium citrate.
Mono-, di-, and tripotassium citrate.
Potassium oleate.
Potassium stearate.
Sodium pyrophosphate.
Sodium stearate.
Sodium tetrapyrophosphate.
Stannous stearate (not to exceed 50 parts per million tin as a migrant in finished food).
Zinc orthophosphate (not to exceed 50 parts per million zinc as a migrant in finished food).
Zinc resinate (not to exceed 50 parts per million zinc as a migrant in finished food).

§ 181.30 Substances used in the manufacture of paper and paperboard products used in food packaging.

Substances used in the manufacture of paper and paperboard products used in food packaging shall include:
ulce:nid

Aliphatic polyoxyethylene ethers.*
1-Alkyl (C_6-C_{18}) 3-amino-3-aminopropane monoacetate.*
Borax or boric acid for use in adhesives, sizes, and coatings.*
Butadiene-styrene copolymer.
Chromium complex of perfluoro-octane sulfonyl glycine for use on paper and paperboard which is waxed.*
Disodium cyanodithioimidocarbamate with ethylene diamine and potassium *N*-methyl dithiocarbamate and/or sodium 2-mercaptobenzothiazole (slimicides).*
Ethyl acrylate and methyl methacrylate copolymers of itaconic acid or methacrylic acid for use only on paper and paperboard which is waxed.*
Hexamethylene tetramine as a setting agent for protein, including casein.*
1-(2-Hydroxyethyl)-1-(4-chlorobutyl)-2-alkyl (C_6-C_{17}) imidazolinium chloride.*
Itaconic acid (polymerized).
Melamine formaldehyde polymer.
Methyl acrylate (polymerized).
Methyl ethers or mono-, di-, and tripropylene glycol.*
Myristo chromic chloride complex.
Nitrocellulose.
Polyethylene glycol 400.
Polyvinyl acetate.
Potassium pentachlorophenate as a slime control agent.*
Potassium trichlorophenate as a slime control agent.*
Resins from high and low viscosity polyvinyl alcohol for fatty foods only.
Rubber hydrochloride.
Sodium pentachlorophenate as a slime control agent.*
Sodium-trichlorophenate as a slime control agent.*
Stearato-chromic chloride complex.
Titanium dioxide.*
Urea formaldehyde polymer.
Vinylidine chlorides (polymerized).

*Under the conditions of normal use, these substances would not reasonably be expected to migrate to food, based on available scientific information and data.

§ 181.32 Acrylonitrile copolymers and resins.

(a) Acrylonitrile copolymers and resins listed in this section, containing less than 30 percent acrylonitrile and complying with the requirements of paragraph (b) of this section, may be safely used as follows:

(1) *Films.* (i) Acrylonitrile/butadiene/styrene copolymers—no restrictions.

(ii) Acrylonitrile/butadiene/styrene copolymers—no restrictions.

(iii) Acrylonitrile/butadiene copolymer blended with vinyl chloride-vinyl acetate (optional at level up to 5 percent by weight of the vinyl chloride resin) resin—for use only in contact with oleomargarine.

(iv) Acrylonitrile/styrene copolymer—no restrictions.

(2) *Coatings.* (i) Acrylonitrile/butadiene copolymer blended with polyvinyl chloride resins—for use only on paper and paperboard in contact with meats and lard.

(ii) Polyvinyl chloride resin blended with either acrylonitrile/butadiene copolymer or acrylonitrile/butadiene styrene copolymer mixed with neoprene, for use as components of conveyor belts to be used with fresh fruits, vegetables, and fish.

(iii) Acrylonitrile/butadiene/styrene copolymer—no restrictions.

(iv) Acrylonitrile/styrene copolymer—no restrictions.

(3) *Rigid and semirigid containers.* (i) Acrylonitrile/butadiene/styrene copolymer—for use only as piping for handling food products and for repeated-use articles intended to contact food.

(ii) Acrylonitrile/styrene resin—no restrictions.

(iii) Acrylonitrile/butadiene copolymer blended with polyvinyl chloride resin—for use only as extruded pipe.

(b) Limitations for acrylonitrile monomer extraction for finished food-contact articles, determined by using methods of analysis available upon request from the Food and Drug Administration, Bureau of Foods, Division of Food and Color Additives, 200 C St. SW., Washington, DC 20204, are as follows:

(1) In the case of single-use articles having a volume to surface ratio of 10 milliliters or more per square inch of food-contact surface—0.003 milligram/square inch when extracted to equilibrium at 120° F with food-simulating solvents appropriate to the intended conditions of use.

(2) In the case of single-use articles having a volume to surface ratio of less than 10 milliliters per square inch of food-contact surface—0.3 part per million calculated on the basis of the volume of the container when extracted to equilibrium at 120° F with food-simulating solvents appropriate to the intended conditions of use.

(3) In the case of repeated-use articles—0.003 milligram/square inch when extracted at a time equivalent to initial batch usage utilizing food-simulating solvents and temperatures appropriate to the intended conditions of use.

The food-simulating solvents shall include, where applicable, distilled water, 8 percent or 50 percent ethanol, 3 percent acetic acid, and either *n*-heptane or an appropriate oil or fat.

(c) Acrylonitrile monomer may present a hazard to health when ingested. Accordingly, any food-contact article containing acrylonitrile copolymers or resins that yield acrylonitrile monomer in excess of that amount provided for in paragraph (b) of this section shall be deemed to be adulterated in violation of section 402 of the act.

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

Subpart A—General Provisions

Sec.
182.1 Substances that are generally recognized as safe.
182.10 Spices and other natural seasonings and flavorings.
182.20 Essential oils, oleoresins (solvent-free), and natural extractives (including distillates).
182.30 Natural substances used in conjunction with spices and other natural seasonings and flavorings.
182.40 Natural extractives (solvent-free) used in conjunction with spices, seasonings, and flavorings.
182.50 Certain other spices, seasonings, essential oils, oleoresins, and natural extracts.
182.60 Synthetic flavoring substances and adjuvants.
182.70 Substances migrating from cotton fabrics used in dry food packaging.
182.90 Substances migrating to food from paper and paperboard products.
182.99 Adjuvants for pesticide chemicals.

Subpart B—Multiple Purpose GRAS Food Substances

182.1005 Acetic acid.
182.1009 Adipic acid.
182.1033 Citric acid.
182.1045 Glutamic acid.
182.1047 Glutamic acid hydrochloride.
182.1057 Hydrochloric acid.
182.1061 Lactic acid.
182.1069 Malic acid.
182.1073 Phosphoric acid.
182.1077 Potassium acid tartrate.
182.1087 Sodium acid pyrophosphate.
182.1091 Succinic acid.
182.1095 Sulfuric acid.
182.1099 Tartaric acid.
182.1125 Aluminum sulfate.
182.1127 Aluminum ammonium sulfate.
182.1129 Aluminum potassium sulfate.
182.1131 Aluminum sodium sulfate.
182.1135 Ammonium bicarbonate.
182.1137 Ammonium carbonate.
182.1139 Ammonium hydroxide.
182.1141 Ammonium phosphate.
182.1143 Ammonium sulfate.
182.1155 Bentonite.
182.1165 Butane.
182.1180 Caffeine.
182.1191 Calcium carbonate.
182.1193 Calcium chloride.
182.1195 Calcium citrate.
182.1199 Calcium gluconate.
182.1205 Calcium hydroxide.
182.1207 Calcium lactate.

Sec.
182.1210 Calcium oxide.
182.1217 Calcium phosphate.
182.1235 Caramel.
182.1240 Carbon dioxide.
182.1275 Dextrans.
182.1295 Ethyl formate.
182.1320 Gylcerin.
182.1324 Glyceryl monostearate.
182.1355 Helium.
182.1366 Hydrogen peroxide.
182.1400 Lecithin.
182.1425 Magnesium carbonate.
182.1428 Magnesium hydroxide.
182.1431 Magnesium oxide.
182.1440 Magnesium stearate.
182.1480 Methylcellulose.
182.1500 Monoammonium glutamate.
182.1516 Monopotassium glutamate.
182.1540 Nitrogen.
182.1545 Nitrous oxide.
182.1585 Papain.
182.1613 Potassium bicarbonate.
182.1619 Potassium carbonate.
182.1625 Potassium citrate.
182.1631 Potassium hydroxide.
182.1643 Potassium sulfate.
182.1655 Propane.
182.1666 Propylene glycol.
182.1685 Rennet.
182.1711 Silica aerogel.
182.1721 Sodium acetate.
182.1736 Sodium bicarbonate.
182.1742 Sodium carbonate.
182.1745 Sodium carboxymethylcellulose.
182.1748 Sodium caseinate.
182.1751 Sodium citrate.
182.1763 Sodium hydroxide.
182.1775 Sodium pectinate.
182.1778 Sodium phosphate.
182.1781 Sodium aluminum phosphate.
182.1792 Sodium sesquicarbonate.
182.1804 Sodium potassium tartrate.
182.1810 Sodium tripolyphosphate.
182.1901 Triacetin.
182.1911 Triethyl citrate
182.1973 Beeswax.
182.1975 Bleached beeswax.
182.1978 Carnauba wax.

Subpart C—Anticaking Agents

182.2122 Aluminum calcium silicate.
182.2227 Calcium silicate.
182.2437 Magnesium silicate.
182.2727 Sodium aluminosilicate.
182.2729 Sodium calcium aluminosilicate, hydrated.
182.1906 Tricalcium silicate.

Subpart D—Chemical Preservatives

182.3013 Ascorbic acid.
182.3025 Caprylic acid.
182.3041 Erythorbic acid.
182.3081 Propionic acid.
182.3089 Sorbic acid.
182.3109 Thiodipropionic acid.
182.3149 Ascorbyl palmitate.
182.3169 Butylated hydroxyanisole.
182.3173 Butylated hydroxytoluene.
182.3189 Calcium ascorbate.
182.3221 Calcium propionate.
182.3225 Calcium sorbate.
182.3280 Dilauryl thiodipropionate.
182.3336 Gum guaiac.
182.3616 Potassium bisulfite.
182.3637 Potassium metabisulfite.
182.3640 Potassium sorbate.
182.3731 Sodium ascorbate.
182.3739 Sodium bisulfite.
182.3766 Sodium metabisulfite.
182.3784 Sodium propionate.
182.3795 Sodium sorbate.
182.3798 Sodium sulfite.
182.3845 Stannous chloride.
182.3862 Sulfur dioxide.
182.3890 Tocopherols.

Subpart E—Emulsifying Agents

Sec.
182.4029 Cholic acid.
182.4037 Desoxycholic acid.
182.4053 Glycocholic acid.
182.4101 Diacetyl tartaric acid esters of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.
182.4105 Taurocholic acid.
182.4505 Mono- and diglycerides of edible fats or oils, or edible fat-forming acids.
182.4521 Monosodium phosphate derivatives of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.
182.4560 Ox bile extract.
182.4666 Propylene glycol.

Subpart F—Nutrients and or Dietary Supplements

182.5013 Ascorbic acid.
182.5017 Aspartic acid.
182.5049 Aminoacetic acid (glycine).
182.5065 Linoleic acid.
182.5118 Alanine.
182.5145 Arginine.
182.5159 Biotin.
182.5191 Calcium carbonate.
182.5195 Calcium citrate.
182.5201 Calcium glycerophosphate.
182.5210 Calcium oxide.
182.5212 Calcium pantothenate.
182.5217 Calcium phosphate.
182.5223 Calcium pyrophosphate.
182.5230 Calcium sulfate.
182.5245 Carotene.
182.5250 Choline bitartrate.
182.5252 Choline chloride.
182.5260 Copper gluconate.
182.5265 Cuprous iodide.
182.5278 Cystine.
182.5301 Ferric phosphate.
182.5304 Ferric pyrophosphate.
182.5306 Ferric sodium pyrophosphate.
182.5308 Ferrous gluconate.
182.5311 Ferrous lactate.
182.5315 Ferrous sulfate.
182.5361 Histidine.
182.5370 Inositol.
182.5375 Iron reduced.
182.5381 Isoleucine.
182.5406 Leucine.
182.5411 Lysine.
182.5431 Magnesium oxide.
182.5434 Magnesium phosphate.
182.5443 Magnesium sulfate.
182.5446 Manganese chloride.
182.5449 Manganese citrate.
182.5452 Manganese gluconate.
182.5455 Manganese glycerophosphate.
182.5458 Manganese hypophosphite.
182.5461 Manganese sulfate.
182.5464 Manganous oxide.
182.5470 Mannitol.
182.5475 Methionine.
182.5477 Methionine hydroxy analog and its calcium salts.
182.5530 Niacin.
182.5535 Niacinamide.
182.5580 D-Pantothenyl alcohol.
182.5590 Phenylalanine.
182.5622 Potassium chloride.
182.5628 Potassium glycerophosphate.
182.5634 Potassium iodide.
182.5650 Proline.
182.5676 Pyridoxine hydrochloride.
182.5695 Riboflavin.
182.5697 Riboflavin-5-phosphate.
182.5701 Serine.
182.5772 Sodium pantothenate.
182.5778 Sodium phosphate.
182.5875 Thiamine hydrochloride.
182.5878 Thiamine mononitrate.
182.5881 Threonine.
182.5890 Tocopherols.
Sec.
182.5892 α-Tocopherol acetate.
182.5915 Tryptophane.
182.5920 Tyrosine.
182.5925 Valine.
182.5930 Vitamin A.
182.5933 Vitamin A acetate.
182.5936 Vitamin A palmitate.
182.5945 Vitamine B_{12}.
182.5950 Vitamin D_2.
182.5953 Vitamin D_3.
182.5985 Zinc chloride.
182.5988 Zinc gluconate.
182.5991 Zinc oxide.
182.5994 Zinc stearate.
182.5997 Zinc sulfate.

Subpart G—Sequestrants

182.6033 Citric acid.
182.6085 Sodium acid phosphate.
182.6099 Tartaric acid.
182.6185 Calcium acetate.
182.6193 Calcium chloride.
182.6195 Calcium citrate.
182.6197 Calcium diacetate.
182.6199 Calcium gluconate.
182.6203 Calcium hexametaphosphate.
182.6215 Monobasic calcium phosphate.
182.6219 Calcium phytate.
182.6285 Dipotassium phosphate.
182.6290 Disodium phosphate.
182.6386 Isopropyl citrate.
182.6511 Monoisopropyl citrate.
182.6625 Potassium citrate.
182.6751 Sodium citrate.
182.6754 Sodium diacetate.
182.6757 Sodium gluconate.
182.6760 Sodium hexametaphosphate.
182.6769 Sodium metaphosphate.
182.6778 Sodium phosphate.
182.6787 Sodium pyrophosphate.
182.6789 Tetra sodium pyrophosphate.
182.6801 Sodium tartrate.
182.6804 Sodium potassium tartrate.
182.6807 Sodium thiosulfate.
182.6810 Sodium tripolyphosphate.
182.6851 Stearyl citrate.

Subpart H—Stabilizers

182.7115 Agar-agar.
182.7133 Ammonium alginate.
182.7187 Calcium alginate.
182.7255 Chondrus extract.
182.7610 Potassium alginate.
182.7724 Sodium alginate.

AUTHORITY: Secs. 409, 701, 52 Stat. 1055–1056 as amended, 72 Stat. 1785–1788 as amended (21 U.S.C. 348, 371), unless otherwise noted.

Subpart A—General Provisions

§ 182.1 Substances that are generally recognized as safe.

(a) It is impracticable to list all substances that are generally recognized as safe for their intended use. However, by way of illustration, the Commissioner regards such common food ingredients as salt, pepper, sugar, vinegar, baking powder, and monosodium glutamate as safe for their intended use. This part includes additional substances that, when used for the purposes indicated, in accordance with good manufacturing practice, are regarded by the Commissioner as generaly recognized as safe for such uses.

(b) For the purposes of this section, good manufacturing practice shall be defined to include the following restrictions:

(1) The quantity of a substance added to food does not exceed the amount reasonably required to accomplish its in-

tended physical, nutritional, or other technical effect in food; and

(2) The quantity of a substance that becomes a component of food as a result of its use in the manufacturing, processing, or packaging of food, and which is not intended to accomplish any physical or other technical effect in the food itself, shall be reduced to the extent reasonably possible.

(3) The substance is of appropriate food grade and is prepared and handled as a food ingredient. Upon request the Commissioner will offer an opinion, based on specifications and intended use, as to whether or not a particular grade or lot of the substance is of suitable purity for use in food and would generally be regarded as safe for the purpose intended, by experts qualified to evaluate its safety.

(c) The inclusion of substances in the list of nutrients does not constitute a finding on the part of the Department that the substance is useful as a supplement to the diet for humans.

(d) Substances that are generally recognized as safe for their intended use within the meaning of section 409 of the act are listed in this part. When the status of a substance has been reevaluated, it will be deleted from this part, and will be issued as a new regulation under the appropriate part, e.g., "affirmed as GRAS" under Part 184 or 186 of this chapter; "food additive regulation" under Parts 170 through 180 of this chapter; "interim food additive regulation" under Part 180 of this chapter; or "prohibited from use in food" under Part 189 of this chapter.

§ 182.10 Spices and other natural seasonings and flavorings.

Spices and other natural seasonings and flavorings that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Common name	*Botanical name of plant source*
Alfalfa herb and seed	Medicago sativa L.
Allspice	Pimenta officinalis Lindl.
Ambrette seed	Hibiscus abelmoschus L.
Angelica	Angelica archangelica L. or other spp. of Angelica.
Angelica root	Do.
Angelica seed	Do.
Angostura (cusparia bark)	Galipea officinalis Hancock.
Anise	Pimpinella anisum L.
Anise, star	Illicium verum Hook. f.
Balm (lemon balm)	Melissa officinalis L.
Basil, bush	Ocimum minimum L.
Basil, sweet	Ocimum basilicum L.
Bay	Laurus nobilis L.
Calendula	Calendula officinalis L.
Camomile (chamomile), English or Roman	Anthemis nobilis L.
Camomile (chamomile), German or Hungarian	Matricaria chamomilla L.
Capers	Capparis spinosa L.
Capsicum	Capsicum frutescens L. or Capsicum annuum L.
Caraway	Carum carvi L.
Caraway, black (black cumin)	Nigella sativa L.
Cardamom (cardamon)	Elettaria cardamomum Maton.
Cassia, Chinese	Cinnamomum cassia Blume.
Cassia, Padang or Batavia	Cinnamomum burmanni Blume.
Cassia, Saigon	Cinnamomum loureirii Nees.
Cayenne pepper	Capsicum frutescens L. or Capsicum annuum L.
Celery seed	Apium graveolens L.
Chervil	Anthriscus cerefolium (L.) Hoffm.
Chives	Allium schoenoprasum L.
Cinnamon, Ceylon	Cinnamomum zeylanicum Nees.
Cinnamon, Chinese	Cinnamomum cassia Blume.
Cinnamon, Saigon	Cinnamomum loureirii Nees.
Clary (clary sage)	Salvia sclarea L.
Clover	Trifolium spp.
Cloves	Eugenia caryophyllata Thunb.
Coriander	Coriandrum sativum L.
Cumin (cummin)	Cuminum cyminum L.
Cumin, black (black caraway)	Nigella sativa L.
Elder flowers	Sambucus canadensis L.
Fennel, common	Foeniculum vulgare Mill.
Fennel, sweet (finocchio, Florence fennel)	Foeniculum vulgare Mill. var. dulce (DC.) Alex.
Fenugreek	Trigonella foenum-graecum L.
Galanga (galangal)	Alpinia officinarum Hance.
Geranium	Pelargonium spp.
Ginger	Zingiber officinale Rosc.
Glycyrrhiza	Glycyrrhiza glabra L. and other spp. of Glycyrrhiza.
Grains of paradise	Amomum melegueta Rosc.
Horehound (hoarhound)	Marrubium vulgare L.
Horseradish	Armoracia lapathifolia Gilib.
Hyssop	Hyssopus officinalis L.
Lavender	Lavandula officinalis Chaix.
Licorice	Glycyrrhiza glabra L. and other spp. of Glycyrrhiza.
Linden flowers	Tilia spp.
Mace	Myristica fragrans Houtt.
Marigold, pot	Calendula officinalis L.
Marjoram, pot	Majorana onites (L.) Benth.
Marjoram, sweet	Majorana hortensis Moench.
Mustard, black or brown	Brassica nigra (L.) Koch.
Mustard, brown	Brassica juncea (L.) Coss.
Mustard, white or yellow	Brassica hirta Moench.
Nutmeg	Myristica fragrans Houtt.
Oregano (oreganum, Mexican oregano, Mexican sage, origan).	Lippia spp.
Paprika	Capsicum annuum L.
Parsley	Petroselinum crispum (Mill.) Mansf.
Pepper, black	Piper nigrum L.
Pepper, cayenne	Capsicum frutescens L. or Capsicum annum L.
Pepper, red	Do.
Pepper, white	Piper nigrum L.
Peppermint	Mentha piperita L.
Poppy seed	Papayer somniferum L.
Pot marigold	Calendula officinalis L.
Pot marjoram	Majorana onites (L.) Benth.
Rosemary	Rosmarinus officinalis L.

Common name	Botanical name of plant source
Rue	Ruta graveolens L.
Saffron	Crocus sativus L.
Sage	Salvia officinalis L.
Sage, Greek	Salvia triloba L.
Savory, summer	Satureia hortensis L. (Satureja).
Savory, winter	Satureia montana L. (Satureja).
Sesame	Sesamum indicum L.
Spearmint	Mentha spicata L.
Star anise	Illicium verum Hook. f.
Tarragon	Artemisia dracunculus L.
Thyme	Thymus vulgaris L.
Thyme, wild or creeping	Thymus serpyllum L.
Turmeric	Curcuma longa L.
Vanilla	Vanilla planifolia Andr. or Vanilla tahitensis J. W. Moore.
Zedoary	Curcuma zedoaria Rosc.

§ 182.20 Essential oils, oleoresins (solvent-free), and natural extractives (including distillates).

Essential oils, oleoresins (solvent-free), and natural extractives (including distillates) that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Alfalfa	Medicago sativa L.
Allspice	Pimenta officinalis Lindl.
Almond, bitter (free from prussic acid)	Prunus amygdalus Batsch, Prunus armeniaca L., or Prunus persica (L.) Batsch.
Ambrette (seed)	Hibiscus moschatus Moench.
Angelica root	Angelica archangelica L.
Angelica seed	Do.
Angelica stem	Do.
Angostura (cusparia bark)	Galipea officinalis Hancock.
Anise	Pimpinella anisum L.
Asafetida	Ferula assa-foetida L. and related spp. of Ferula.
Balm (lemon balm)	Melissa officinalis L.
Balsam of Peru	Myroxylon pereirae Klotzsch.
Basil	Ocimum basilicum L.
Bay leaves	Laurus nobilis L.
Bay (myrcia oil)	Pimenta racemosa (Mill.) J. W. Moore.
Bergamot (bergamot orange)	Citrus aurantium L. subsp. bergamia Wright et Arn.
Bitter almond (free from prussic acid)	Prunus amygdalus Batsch, Prunus armeniaca L., or Prunus persica (L.) Batsch.
Bois de rose	Aniba rosaeodora Ducke.
Cacao	Theobroma cacao L.
Camomile (chamomile) flowers, Hungarian	Matricaria chamomilla L.
Camomile (chamomile) flowers, Roman or English	Anthemis nobilis L.
Cananga	Cananga odorata Hook. f. and Thoms.
Capsicum	Capsicum frutescens L. and Capsicum annuum L.
Caraway	Carum carvi L.
Cardamom seed (cardamon)	Elettaria cardamomum Maton.
Carob bean	Ceratonia siliqua L.
Carrot	Daucus carota L.
Cascarilla bark	Croton eluteria Benn.
Cassia bark, Chinese	Cinnamomum cassia Blume.
Cassia bark, Padang or Batavia	Cinnamomum burmanni Blume.
Cassia bark, Saigon	Cinnamomum loureirii Nees.
Celery seed	Apium graveolens L.
Cherry, wild, bark	Prunus serotina Ehrh.
Chervil	Anthriscus cerefolium (L.) Hoffm.
Chicory	Cichorium intybus L.
Cinnamon bark, Ceylon	Cinnamomum zeylanicum Nees.
Cinnamon bark, Chinese	Cinnamomum cassia Blume.
Cinnamon bark, Saigon	Cinnamomum loureirii Nees.
Cinnamon leaf, Ceylon	Cinnamomum zeylanicum Nees.
Cinnamon leaf, Chinese	Cinnamomum cassia Blume.
Cinnamon leaf, Saigon	Cinnamomum loureirii Nees.
Citronella	Cymbopogon nardus Rendle.
Citrus peels	Citrus spp.
Clary (clary sage)	Salvia sclarea L.
Clove bud	Eugenia caryophyllata Thunb.
Clove leaf	Do.
Clove stem	Do.
Clover	Trifolium spp.
Coca (decocainized)	Erythroxylum coca Lam. and other spp. of Erythroxylum.
Coffee	Coffea spp.
Cola nut	Cola acuminata Schott and Endl., and other spp. of Cola.
Coriander	Coriandrum sativum L.
Corn silk	Zea mays L.
Cumin (cummin)	Cuminum cyminum L.
Curacao orange peel (orange, bitter peel)	Citrus aurantium L.
Cusparia bark	Galipea officinalis Hancock.
Dandelion	Taraxacum officinale Weber and T. laevigatum DC.
Dandelion root	Do.
Dog grass (quackgrass, triticum)	Agropyron repens (L.) Beauv.
Elder flowers	Sambucus canadensis L. and S. nigra L.
Estragole (esdragol, esdragon, tarragon)	Artemisia dracunculus L.
Estragon (tarragon)	Do.
Fennel, sweet	Foeniculum vulgare Mill.
Fenugreek	Trigonella foenum-graecum L.
Galanga (galangal)	Alpinia officinarum Hance.
Geranium	Pelargonium spp.
Geranium, East Indian	Cymbopogon martini Stapf.
Geranium, rose	Pelargonium graveolens L'Her.
Ginger	Zingiber officinale Rosc.
Glycyrrhiza	Glycyrrhiza glabra L. and other spp. of Glycyrrhiza.
Glycyrrhizin, ammoniated	Do.
Grapefruit	Citrus paradisi Macf.
Guava	Psidium spp.
Hickory bark	Carya spp.
Horehound (hoarhound)	Marrubium vulgare L.
Hops	Humulus lupulus L.
Horsemint	Monarda punctata L.
Hyssop	Hyssopus officinalis L.
Immortelle	Helichrysum augustifolium DC.

Common name	*Botanical name of plant source*
Jasmine	Jasminum officinale L. and other spp. of Jasminum.
Juniper (berries)	Juniperus communis L.
Kola nut	Cola acuminata Schott and Endl., and other spp. of Cola.
Laurel berries	Laurus nobilis L.
Laurel leaves	Laurus spp.
Lavender	Lavandula officinalis Chaix.
Lavender, spike	Lavandula latifolia Vill.
Lavandin	Hybrids between Lavandula officinalis Chaix and Lavandula latifolia Vill.
Lemon	Citrus limon (L.) Burm. f.
Lemon balm (see balm).	
Lemon grass	Cymbopogon citratus DC. and Cymbopogon lexuosus Stapf.
Lemon peel	Citrus limon (L.) Burm. f.
Licorice	Glycyrrhiza glabra L. and other spp. of Glycyrrhiza.
Lime	Citrus aurantifolia Swingle.
Linden flowers	Tilia supp.
Locust bean	Ceratonia siliqua L.
Lupulin	Humulus lupulus L.
Mace	Myristica fragrans Houtt.
Malt (extract)	Hordeum vulgare L., or other grains.
Mandarin	Citrus reticulata Blanco.
Marjoram, sweet	Majorana hortensis Moench.
Maté	Ilex paraguariensis St. Hil.
Melissa (see balm).	
Menthol	Mentha supp.
Menthyl acetate	Do.
Molasses (extract)	Saccarum officinarum L.
Mustard	Brassica spp.
Naringin	Citrus paradisi Macf.
Neroli, bigarade	Citrus aurantium L.
Nutmeg	Myristica fragrans Houtt.
Onion	Allium cepa L.
Orange, bitter, flowers	Citrus aurantium L.
Orange, bitter, peel	Do.
Orange leaf	Citrus sinensis (L.) Osbeck.
Orange, sweet	Do.
Orange, sweet, flowers	Do.
Orange, sweet, peel	Do.
Origanum	Origanum spp.
Palmarosa	Cymbopogon martini Stapf.
Paprika	Capsicum annuum L.
Parsley	Petroselinum crispum (Mill.) Mansf.
Pepper, black	Piper nigrum L.
Pepper, white	Do.
Peppermint	Mentha piperita L.
Peruvian balsam	Myroxylon pereirae Klotzsch.
Petitgrain	Citrus aurantium L.
Petitgrain lemon	Citrus limon (L.) Burm. f.
Petitgrain mandarin or tangerine	Citrus reticulata Blanco.
Pimenta	Pimenta officinalis Lindl.
Pimenta leaf	Primenta officinalis Lindl.
Pipsissewa leaves	Chimaphila umbellata Nutt.
Pomegranate	Punica granatum L.
Prickly ash bark	Xanthoxylum (or Zanthoxylum) Americanum Mill. or Xanthoxylum clava-herculis L.
Rose absolute	Rosa alba L., Rosa centifolia L., Rosa damascena Mill., Rosa gallica L., and vars. of these spp.
Rose (otto of roses, attar of roses)	Do.
Rose buds	Do.
Rose flowers	Do.
Rose fruit (hips)	Do.
Rose geranium	Pelargonium graveolens L'Her.
Rose leaves	Rosa spp.
Rosemary	Rosmarinus officinalis L.
Saffron	Crocus sativus L.
Sage	Salvia officinalis L.
Sage, Greek	Salvia triloba L.
Sage, Spanish	Salvia lavandulaefolia Vahl.
St. John's bread	Ceratonia siliqua L.
Savory, summer	Satureia hortensis L.
Savory, winter	Satureia montana L.
Schinus molle	Schinus molle L.
Sloe berries (blackthorn berries)	Prunus spinosa L.
Spearmint	Mentha spicata L.
Spike lavender	Lavandula latifolia Vill.
Tamarind	Tamarindus indica L.
Tangerine	Citrus reticulata Blanco.
Tannic acid	Nutgalls of Quercus infectoria Oliver and related spp. of Quercus. Also in many other plants.
Tarragon	Artemisia dracunculus L.
Tea	Thea sinensis L.
Thyme	Thymus vulgaris L. and Thymus zygis var. gracilis Boiss.
Thyme, white	Do.
Thyme, wild or creeping	Thymus serpyllum L.
Triticum (see dog grass).	
Tuberose	Polianthes tuberosa L.
Turmeric	Curcuma longa L.
Vanilla	Vanilla planifolia Andr. or Vanilla tahitensis J. W. Moore.
Violet flowers	Viola odorata L.
Violet leaves	Do.
Violet leaves absolute	Do.
Wild cherry bark	Prunus serotina Ehrh.
Ylang-ylang	Cananga odorata Hook. f. and Thoms.
Zedoary bark	Curcuma zedoaria Rosc.

§ 182.30 Natural substances used in conjunction with spices and other natural seasonings and flavorings.

Natural substances used in conjunction with spices and other natural seasonings and flavorings that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Common name	*Botanical name of plant source*
Algae, brown (kelp)	Laminaria spp. and Nereocystis spp.
Algae, red	Porphyra spp. and Rhodymenia palmata (L.) Grev.
Dulse	Rhodymenia palmata (L.)

§ 182.40 Natural extractives (solvent-free) used in conjunction with spices, seasonings, and flavorings.

Natural extractives (solvent-free) used in conjunction with spices, seasonings, and flavorings that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Common name	*Botanical name of plant source*
Algae, brown	Laminaria spp. and Nereocystis spp.
Algae, red	Porphyra spp. and Rhodymenia palmata (L.) Grev.
Apricot kernel (persic oil)	Prunus armeniaca L.
Dulse	Rhodymenia palmata (L.) Grev.
Kelp (see algae, brown).	
Peach kernel (persic oil)	Prunus persica Sieb. et Zucc.
Peanut stearine	Arachis hypogaea L.
Persic oil (see apricot kernel and peach kernel).	
Quince seed	Cydonia oblonga Miller.

§ 182.50 Certain other spices, seasonings, essential oils, oleoresins, and natural extracts.

Certain other spices, seasonings, essential oils, oleoresins, and natural extracts that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Common name	*Derivation*
Ambergris	Physeter macrocephalus L.
Castoreum	Castor fiber L. and C. canadensis Kuhl.
Civet (zibeth, zibet, zibetum)	Civet cats, Viverra civetta Schreber and Viverra zibetha Schreber.
Cognac oil, white and green	Ethyl oenanthate, so-called.
Musk (Tonquin musk)	Musk deer, Moschus moschiferus L.

§ 182.60 Synthetic flavoring substances and adjuvants.

Synthetic flavoring substances and adjuvants that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Acetaldehyde (ethanal).
Acetoin (acetyl methylcarbinol).
Aconitic acid (equisetic acid, citridic acid achilleic acid).
Anethole (parapropenyl anisole).
Benzaldehyde (benzoic aldehyde).
N-Butyric acid (butanoic acid).
d- or *l*-Carvone (carvol).
Cinnamaldehyde (cinnamic aldehyde).
Citral (2,6-dimethyloctadien-2,6-*al*-8, geranial, neral).
Decanal (*N*-decylaldehyde, capraldehyde, capric aldehyde, caprinaldehyde, aldehyde C-10).
Diacetyl (2,3-butandeione).
Ethyl acetate.
Ethyl butyrate.
3-Methyl-3-phenyl glycidic acid ethyl ester (ethyl-methyl-phenyl-glycidate, so-called strawberry aldehyde, C-16 aldehyde).
Ethyl vanillin.
Eugenol.
Geraniol (3,7-dimethyl-2,6 and 3,6-octadien-1-*ol*).
Geranyl acetate (geraniol acetate).
Glycerol (glyceryl) tributyrate (tributyrin, butyrin).
Limonene (*d*-, *l*-, and *dl*-).
Linalool (linalol, 3,7-dimethyl-1,6-octadien-3-*ol*).
Linalyl acetate (bergamol).
l-Malic acid.
Methyl anthranilate (methyl-2-aminobenzoate).
Piperonal (3,4-methylenedioxy-benzaldehyde, heliotropin).
Vanillin.

§ 182.70 Substances migrating from cotton and cotton fabrics used in dry food packaging.

Substances migrating to food from cotton and cotton fabrics used in dry food packaging that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Acetic acid.
Beef tallow.
Calcium chloride.
Carboxymethylcellulose.
Coconut oil, refined.
Corn dextrin.
Cornstarch.
Fish oil (hydrogenated).
Gelatin.
Hydrogen peroxide.
Japan wax.
Lard.
Lard oil.
Lecithin (vegetable).
Oleic acid.
Peanut oil.
Potato starch.
Sodium acetate.
Sodium bicarbonate.
Sodium carbonate.
Sodium chloride.
Sodium hydroxide.
Sodium sulfate.
Sodium silicate.
Sodium tripolyphosphate.
Sorbose.
Soybean oil (hydrogenated).
Stearic acid.
Talc.
Tall oil.
Tallow (hydrogenated).
Tallow flakes.
Tapioca starch.
Tartaric acid.
Tetrasodium pyrophosphate.
Urea.
Wheat starch.
Zinc chloride.

§ 182.90 Substances migrating to food from paper and paperboard products.

Substances migrating to food from paper and paperboard products used in food packaging that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

Acetic acid.
Alum (double sulfate of aluminum and ammonium potassium, or sodium).
Aluminum hydroxide.
Aluminum oleate.
Aluminum palmitate.
Ammonium chloride.
Ammonium hydroxide.
Calcium chloride.
Calcium hydroxide (lime).
Calcium sulfate.
Casein.
Cellulose acetate.
Clay (kaolin).
Copper sulfate.
Cornstarch.
Corn sugar (sirup).
Dextrin.
Diatomaceous earth filler.
Ethyl cellulose.
Ethyl vanillin.
Ferric sulfate.
Ferrous sulfate.
Formic acid or sodium salt.
Glycerin.
Invert sugar.
Iron, reduced.
Magnesium carbonate.
Magnesium chloride.
Magnesium hydroxide.
Magnesium sulfate.
Methyl and ethyl acrylate.
Mono- and digylcerides from glycerolysis of edible fats and oils.
Oleic acid.
Oxides of iron.
Potassium sorbate.
Propionic acid.
Propylene glycol.
Silicon dioxides.
Soap (sodium oleate, sodium palmitate).
Sodium aluminate.
Sodium carbonate.
Sodium chloride.
Sodium hexametaphosphate.
Sodium hydrosulfite.
Sodium hydroxide.
Sodium phosphoaluminate.
Sodium silicate.
Sodium sorbate.
Sodium sulfate.
Sodium thiosulfate (additive in salt).
Sodium tripolyphosphate.
Sorbitol.
Soy protein, isolated.
Sulfamic acid.
Sulfuric acid.
Starch, acid modified.
Starch, pregelatinized.
Starch, unmodified.
Sucrose.
Talc.
Urea.
Vanillin.
Zinc hydrosulfite.
Zinc sulfate.

§ 182.99 Adjuvants for pesticide chemicals.

Adjuvants, identified and used in accordance with 40 CFR 180.1001 (c) and (d), which are added to pesticide use dilutions by a grower or applicator prior to application to the raw agricultural commodity, are exempt from the requirement of tolerances under section 409 of the act.

(Sec. 409, 72 Stat. 1785; 21 U.S.C. 348.)

Subpart B—Multiple Purpose GRAS Food Substances

§ 182.1005 Acetic acid.

(a) *Product.* Acetic acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1009 Adipic acid.

(a) *Product.* Adipic acid.

(b) [Reserved]

(c) *Limitations, restrictions, or ex-*

planation. This substance is generally recognized as safe when used as a buffer and neutralizing agent in accordance with good manufacturing practice.

§ 182.1033 Citric acid.

(a) *Product.* Citric acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1045 Glutamic acid.

(a) *Product.* Glutamic acid.
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a salt substitute in accordance with good manufacturing practice.

§ 182.1047 Glutamic acid hydrochloride.

(a) *Product.* Glutamic acid hydrochloride.
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a salt substitute in accordance with good manufacturing practice.

§ 182.1057 Hydrochloric acid.

(a) *Product.* Hydrochloric acid.
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a buffer and neutralizing agent in accordance with good manufacturing practice.

§ 182.1061 Lactic acid.

(a) *Product.* Lactic acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1069 Malic acid.

(a) *Product.* Malic acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1073 Phosphoric acid.

(a) *Product.* Phosphoric acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1077 Potassium acid tartrate.

(a) *Product.* Potassium acid tartrate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1087 Sodium acid pyrophosphate.

(a) *Product.* Sodium acid pyrophosphate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1091 Succinic acid.

(a) *Product.* Succinic acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1095 Sulfuric acid.

(a) *Product.* Sulfuric acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1099 Tartaric acid.

(a) *Product.* Tartaric acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1125 Aluminum sulfate.

(a) *Product.* Aluminum sulfate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1127 Aluminum ammonium sulfate.

(a) *Product.* Aluminum ammonium sulfate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1129 Aluminum potassium sulfate.

(a) *Product.* Aluminum potassium sulfate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1131 Aluminum sodium sulfate.

(a) *Product.* Aluminum sodium sulfate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1135 Ammonium bicarbonate.

(a) *Product.* Ammonium bicarbonate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1137 Ammonium carbonate.

(a) *Product.* Ammonium carbonate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1139 Ammonium hydroxide.

(a) *Product.* Ammonium hydroxide.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1141 Ammonium phosphate.

(a) *Product.* Ammonium phosphate (mono- and dibasic).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1143 Ammonium sulfate.

(a) *Product.* Ammonium sulfate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1155 Bentonite.

(a) *Product.* Bentonite.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1165 Butane.

(a) *Product.* Butane.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1180 Caffeine.

(a) *Product.* Caffeine.
(b) *Tolerance.* 0.02 percent.
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in cola-type beverages in accordance with good manufacturing practice.

§ 182.1191 Calcium carbonate.

(a) *Product.* Calcium carbonate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1193 Calcium chloride.

(a) *Product.* Calcium chloride.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1195 Calcium citrate.

(a) *Product.* Calcium citrate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1199 Calcium gluconate.

(a) *Product.* Calcium gluconate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1205 Calcium hydroxide.

(a) *Product.* Calcium hydroxide.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1207 Calcium lactate.

(a) *Product.* Calcium lactate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1210 Calcium oxide.

(a) *Product.* Calcium oxide.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1217 Calcium phosphate.

(a) *Product.* Calcium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1235 Caramel.

(a) *Product.* Caramel.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1240 Carbon dioxide.

(a) *Product.* Carbon dioxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1275 Dextrans.

(a) *Product.* Dextrans of average molecular weight below 100,000.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1295 Ethyl formate.

(a) *Product.* Ethyl formate.

(b) *Tolerance.* 0.0015 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as fumigant for cashew nuts in accordance with good manufacturing practice.

§ 182.1320 Glycerin.

(a) *Product.* Glycerin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1324 Glyceryl monostearate.

(a) *Product.* Glyceryly monostearate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1355 Helium.

(a) *Product.* Helium.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1366 Hydrogen peroxide.

(a) *Product.* Hydrogen peroxide.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a bleaching agent in accordance with good manufacturing practice.

§ 182.1400 Lecithin.

(a) *Product.* Lecithin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1425 Magnesium carbonate.

(a) *Product.* Magnesium carbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1428 Magnesium hydroxide.

(a) *Product.* Magnesium hydroxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1431 Magnesium oxide.

(a) *Product.* Magnesium oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1440 Magnesium stearate.

(a) *Product.* Magnesium stearate.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as migratory substance from packaging materials when used as a stabilizer in accordance with good manufacturing practice.

§ 182.1480 Methylcellulose.

(a) *Product.* U.S.P. methylcellulose, except that the methoxy content shall not be less than 27.5 percent and not more than 31.5 percent on a dry-weight basis.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1500 Monoammonium glutamate.

(a) *Product.* Monoammonium glutamate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1516 Monopotassium glutamate.

(a) *Product.* Monopotassium glutamate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1540 Nitrogen.

(a) *Product.* Nitrogen.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1545 Nitrous oxide.

(a) *Product.* Nitrous oxide.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a propellant for certain dairy and vegetable-fat toppings in pressurized containers in accordance with good manufacturing practice.

§ 182.1585 Papain.

(a) *Product.* Papain.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1613 Potassium bicarbonate.

(a) *Product.* Potassium bicarbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1619 Potassium carbonate.

(a) *Product.* Potassium carbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1625 Potassium citrate.

(a) *Product.* Potassium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1631 Potassium hydroxide.

(a) *Product.* Potassium hydroxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1643 Potassium sulfate.

(a) *Product.* Potassium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1655 Propane.

(a) *Product.* Propane.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1666 Propylene glycol.

(a) *Product.* Propylene glycol.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1685 Rennet.

(a) *Product. Rennet* (rennin).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1711 Silica aerogel.

(a) *Product.* Silica aerogel as a finely powdered microcellular silica foam having a minimum silica content of 89.5 percent.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a component of an anti-foaming agent in accordance with good manufacturing practice.

§ 182.1721 Sodium acetate.

(a) *Product.* Sodium acetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1736 Sodium bicarbonate.

(a) *Product.* Sodium bicarbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1742 Sodium carbonate.

(a) *Product.* Sodium carbonate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1745 Sodium carboxymethylcellulose.

(a) *Product.* Sodium carboxymethylcellulose is the sodium salt of carboxymethylcellulose not less than 99.5 percent on a dry-weight basis, with maximum substitution of 0.95 carboxymethyl groups per anhydroglucose unit, and with a minimum viscosity of 25 centipoises for 2 percent by weight aqueous solution at 25° C.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1748 Sodium caseinate.

(a) *Product.* Sodium caseinate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1751 Sodium citrate.

(a) *Product.* Sodium citrate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1763 Sodium hydroxide.

(a) *Product.* Sodium hydroxide.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1775 Sodium pectinate.

(a) *Product.* Sodium pectinate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1778 Sodium phosphate.

(a) *Product.* Sodium phosphate (mono-, di-, and tribasic).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1781 Sodium aluminum phosphate.

(a) *Product.* Sodium aluminum phosphate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1792 Sodium sesquicarbonate.

(a) *Product.* Sodium sesquicarbonate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1804 Sodium potassium tartrate.

(a) *Product.* Sodium potassium tartrate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1810 Sodium tripolyphosphate.

(a) *Product.* Sodium tripolyphosphate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1901 Triacetin.

(a) *Product.* Triacetin (glyceryl triacetate).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1911 Triethyl citrate.

(a) *Product.* Triethyl citrate.
(b) *Tolerance.* 0.25 percent.
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in dried egg whites in accordance with good manufacturing practice.

§ 182.1973 Beeswax.

(a) *Product.* Beeswax (yellow wax).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1975 Bleached beeswax.

(a) *Product.* Bleached beeswax (white wax).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1978 Carnauba wax.

(a) *Product.* Carnauba wax.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

Subpart C—Anticaking Agents

§ 182.2122 Aluminum calcium silicate.

(a) *Product.* Aluminum calcium silicate.
(b) *Tolerance.* 2 percent.
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt in accordance with good manufacturing practice.

§ 182.2227 Calcium silicate.

(a) *Product.* Calcium silicate.
(b) *Tolerance.* 2 percent and 5 percent.
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used at levels not exceeding 2 percent in table salt and 5 percent in baking powder in accordance with good manufacturing practice.

§ 182.2437 Magnesium silicate.

(a) *Product.* Magnesium silicate.
(b) *Tolerance.* 2 percent.
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt in accordance with good manufacturing practice.

§ 182.2727 Sodium aluminosilicate.

(a) *Product.* Sodium aluminosilicate (sodium silicoaluminate).
(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 2 percent in accordance with good manufacturing practice.

§ 182.2729 Sodium calcium aluminosilicate, hydrated.

(a) *Product.* Hydrated sodium calcium aluminosilicate (sodium calcium silicoaluminate).
(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 2 percent in accordance with good manufacturing practice.

§ 182.2906 Tricalcium silicate.

(a) *Product.* Tricalcium silicate.
(b) *Tolerance.* 2 percent.
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt in accordance with good manufacturing practice.

Subpart D—Chemical Preservatives

§ 182.3013 Ascorbic acid.

(a) *Product.* Ascorbic acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3025 Caprylic acid.

(a) *Product.* Caprylic acid.
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in cheese wraps in accordance with good manufacturing practice.

§ 182.3041 Erythorbic acid.

(a) *Product.* Erythorbic acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3081 Propionic acid.

(a) *Product.* Propionic acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3089 Sorbic acid.

(a) *Product.* Sorbic acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3109 Thiodipropionic acid.

(a) *Product.* Thiodipropionic acid.
(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil con-

tent, including essential (volatile) oil content of the food, provided the substance is used in accordance with good manufacturing practice.

§ 182.3149 Ascorbyl palmitate.

(a) *Product.* Ascorbyl palmitate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3169 Butylated hydroxyanisole.

(a) *Product.* Butylated hydroxyanisole.
(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of food, provided the substance is used in accordance with good manufacturing practice.

§ 182.3173 Butylated hydroxytoluene.

(a) *Product.* Butylated hydroxytoluene.
(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of food, provided the substance is used in accordance with good manufacturing practice.

§ 182.3189 Calcium ascorbate.

(a) *Product.* Calcium ascorbate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3221 Calcium propionate.

(a) *Product.* Calcium propionate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3225 Calcium sorbate.

(a) *Product.* Calcium sorbate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3280 Dilauryl thiodipropionate.

(a) *Product.* Dilauryl thiodipropionate.
(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food, provided the substance is used in accordance with good manufacturing practice.

§ 182.3336 Gum guaiac.

(a) *Product.* Gum guaiac.
(b) *Tolerance.* 0.1 percent (equivalent antioxidant activity 0.01 percent).
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in edible fats or oils in accordance with good manufacturing practice.

§ 182.3616 Potassium bisulfite.

(a) *Product.* Potassium bisulfite.
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B_1.

§ 182.3637 Potassium metabisulfite.

(a) *Product.* Potassium metabisulfite.
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B_1.

§ 182.3640 Potassium sorbate.

(a) *Product.* Potassium sorbate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3731 Sodium ascorbate.

(a) *Product.* Sodium ascorbate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3739 Sodium bisulfite.

(a) *Product.* Sodium bisulfite.
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B_1.

§ 182.3766 Sodium metabisulfite.

(a) *Product.* Sodium metabisulfite.
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B_1.

§ 182.3784 Sodium propionate.

(a) *Product.* Sodium propionate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3795 Sodium sorbate.

(a) *Product.* Sodium sorbate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3798 Sodium sulfite.

(a) *Product.* Sodium sulfite.
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B_1.

§ 182.3845 Stannous chloride.

(a) *Product.* Stannous chloride.
(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.0015 percent calculated as tin in accordance with good manufacturing practice.

§ 182.3862 Sulfur dioxide.

(a) *Product.* Sulfur dioxide.
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B_1.

§ 182.3890 Tocopherols.

(a) *Product.* Tocopherols.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

Subpart E—Emulsifying Agents

§ 182.4029 Cholic acid.

(a) *Product.* Cholic acid.
(b) *Tolerance.* 0.1 percent.
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in dried egg whites in accordance with good manufacturing practice.

§ 182.4037 Desoxycholic acid.

(a) *Product.* Desoxycholic acid.
(b) *Tolerance.* 0.1 percent.
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in dried egg whites in accordance with good manufacturing practice.

§ 182.4053 Glycocholic acid.

(a) *Product.* Glycocholic acid.
(b) *Tolerance.* 0.1 percent.
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in dried egg whites in accordance with good manufacturing practice.

§ 182.4101 Diacetyl tartaric acid esters of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.

(a) *Product.* Diacetyl tartaric acid esters of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.4105 Taurocholic acid.

(a) *Product.* Taurocholic acid (or its sodium salt).
(b) *Tolerance.* 0.1 percent.
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in dried egg whites in accordance with good manufacturing practice.

§ 182.4505 Mono- and diglycerides of edible fats or oils, or edible fat-forming acids.

(a) *Product.* Mono- and diglycerides of edible fats or oils, or edible fat-forming acids.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.4521 Monosodium phosphate derivatives of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.

(a) *Product.* Monosodium phosphate derivatives of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.4560 Ox bile extract.

(a) *Product.* Ox bile extract.

(b) *Tolerance.* 0.1 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in dried egg whites in accordance with good manufacturing practice.

§ 182.4666 Propylene glycol.

(a) *Product.* Propylene glycol.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

Subpart F—Nutrients and/or Dietary Supplements [15]

§ 182.5013 Ascorbic acid.

(a) *Product.* Ascorbic acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5017 Aspartic acid.

(a) *Product.* Aspartic acid (L- and DL forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5049 Aminoacetic acid (glycine).

(a) *Product.* Glycine (aminoacetic acid).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5065 Linoleic acid.

(a) *Product.* Linoleic acid prepared from edible fats and oils and free from chickedema factor.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5118 Alanine.

(a) *Product.* Alanine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5145 Arginine.

(a) *Product.* Arginine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5159 Biotin.

(a) *Product.* Biotin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5191 Calcium carbonate.

(a) *Product.* Calcium carbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5195 Calcium citrate.

(a) *Product.* Calcium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5201 Calcium glycerophosphate.

(a) *Product.* Calcium glycerophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5210 Calcium oxide.

(a) *Product.* Calcium oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5212 Calcium pantothenate.

(a) *Product.* Calcium pantothenate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5217 Calcium phosphate.

(a) *Product.* Calcium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5223 Calcium pyrophosphate.

(a) *Product.* Calcium pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5230 Calcium sulfate.

(a) *Product.* Calcium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5245 Carotene.

(a) *Product.* Carotene.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5250 Choline bitartrate.

(a) *Product.* Choline bitartrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5252 Choline chloride.

(a) *Product.* Choline chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5260 Copper gluconate.

(a) *Product.* Copper gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe for use at a level not exceeding 0.005 percent in accordance with good manufacturing practice.

§ 182.5265 Cuprous iodide.

(a) *Products.* Cuprous iodide.

(b) *Tolerance.* 0.01 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt as a source of dietary iodine in accordance with good manufacturing practice.

§ 182.5273 Cystine.

(a) *Product.* Cystine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5301 Ferric phosphate.

(a) *Product.* Ferric phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5304 Ferric pyrophosphate.

(a) *Product.* Ferric pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5306 Ferric sodium pyrophosphate.

(a) *Product.* Ferric sodium pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5308 Ferrous gluconate.

(a) *Product.* Ferrous gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5311 Ferrous lactate.

(a) *Product.* Ferrous lactate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

[15] Amino acids listed in this subpart may be free hydrochloride salt, hydrated, or anhydrous form, where applicable.

§ 182.5315 Ferrous sulfate.

(a) *Product.* Ferrous sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5361 Histidine.

(a) *Product.* Histidine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5370 Inositol.

(a) *Product.* Inositol.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5375 Iron reduced.

(a) *Product.* Iron reduced.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5381 Isoleucine.

(a) *Product.* Isoleucine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5406 Leucine.

(a) *Product.* Leucine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5411 Lysine.

(a) *Product.* Lysine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5431 Magnesium oxide.

(a) *Product.* Magnesium oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5434 Magnesium phosphate.

(a) *Product.* Magnesium phosphate (di- and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5443 Magnesium sulfate.

(a) *Product.* Magnesium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5446 Manganese chloride.

(a) *Product.* Manganese chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5449 Manganese citrate.

(a) *Product.* Manganese citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5452 Manganese gluconate.

(a) *Product.* Manganese gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5455 Manganese glycerophosphate.

(a) *Product.* Manganese glycerophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5458 Manganese hypophosphite.

(a) *Product.* Manganese hypophosphite.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5461 Manganese sulfate.

(a) *Product.* Manganese sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5464 Manganous oxide.

(a) *Product.* Manganous oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5470 Mannitol.

(a) *Product.* Mannitol.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5475 Methionine.

(a) *Product.* Methionine.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5477 Methionine hydroxy analog and its calcium salts.

(a) *Product.* Methionine hydroxy analog and its calcium salts.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5530 Niacin.

(a) *Product.* Niacin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5535 Niacinamide.

(a) *Product.* Niacinamide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5580 D-Pantothenyl alcohol.

(a) *Product.* D-Pantothenyl alcohol.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5590 Phenylalanine.

(a) *Product.* Phenylalanine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5622 Potassium chloride.

(a) *Product.* Potassium chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5628 Potassium glycerophosphate.

(a) *Product.* Potassium glycerophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5634 Potassium iodide.

(a) *Product.* Potassium iodide.

(b) *Tolerance.* 0.01 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt as a source of dietary iodine in accordance with good manufacturing practice.

§ 182.5650 Proline.

(a) *Product.* Proline (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5676 Pyridoxine hydrochloride.

(a) *Product.* Pyridoxine hydrochloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5695 Riboflavin.

(a) *Product.* Riboflavin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice

§ 182.5697 Riboflavin-5-phosphate.

(a) *Product.* Riboflavin-5-phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5701 Serine.

(a) *Product.* Serine (L- and DL-forms).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5772 Sodium pantothenate.

(a) *Product.* Sodium pantothenate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5778 Sodium phosphate.

(a) *Product.* Sodium phosphate (mono-, di-, and tribasic).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5875 Thiamine hydrochloride.

(a) *Product.* Thiamine hydrochloride.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5878 Thiamine mononitrate.

(a) *Product.* Thiamine mononitrate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5881 Threonine.

(a) *Product.* Threonine (L- and DL-forms).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5890 Tocopherols.

(a) *Product.* Tocopherols.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5892 α-Tocopherol acetate.

(a) *Product.* α-Tocopherol acetate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5915 Tryptophane.

(a) *Product.* Tryptophane (L- and DL-forms).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5920 Tyrosine.

(a) *Product.* Tyrosine (L- and DL-forms).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5925 Valine.

(a) *Product.* Valine (L- and DL-forms).
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5930 Vitamin A.

(a) *Product.* Vitamin A.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5933 Vitamin A acetate.

(a) *Product.* Vitamin A acetate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5936 Vitamin A palmitate.

(a) *Product.* Vitamin A palmitate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5945 Vitamin B_{12}.

(a) *Product.* Vitamin B_{12}.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5950 Vitamin D_2.

(a) *Product.* Vitamin D_2.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5953 Vitamin D_3.

(a) *Product.* Vitamin D_3.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5985 Zinc chloride.

(a) *Product.* Zinc chloride.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5988 Zinc gluconate.

(a) *Product.* Zinc gluconate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5991 Zinc oxide.

(a) *Product.* Zinc oxide.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5994 Zinc stearate.

(a) *Product.* Zinc stearate prepared from stearic acid free from chickedema factor.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.5997 Zinc sulfate.

(a) *Product.* Zinc sulfate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

Subpart G—Sequestrants [16]

§ 182.6033 Citric acid.

(a) *Product.* Citric acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6085 Sodium acid phosphate.

(a) *Product.* Sodium acid phosphate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6099 Tartaric acid.

(a) *Product.* Tartaric acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6185 Calcium acetate.

(a) *Product.* Calcium acetate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6193 Calcium chloride.

(a) *Product.* Calcium chloride.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6195 Calcium citrate.

(a) *Product.* Calcium citrate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6197 Calcium diacetate.

(a) *Product.* Calcium diacetate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6199 Calcium gluconate.

(a) *Product.* Calcium gluconate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6203 Calcium hexametaphosphate.

(a) *Product.* Calcium hexametaphosphate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6215 Monobasic calcium phosphate.

(a) *Product.* Monobasic calicum phosphate.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

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[16] For the purpose of this subpart, no attempt has been made to designate those sequestrants that may also function as chemical preservatives.

§ 182.6219 Calcium phytate.

(a) *Product.* Calcium phytate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6285 Dipotassium phosphate.

(a) *Product.* Dipotassium phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6290 Disodium phosphate.

(a) *Product.* Disodium phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6386 Isopropyl citrate.

(a) *Product.* Isopropyl citrate.

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.02 percent in accordance with good manufacturing practice.

§ 182.6511 Monoisopropyl citrate.

(a) *Product.* Monoisopropyl citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6625 Potassium citrate.

(a) *Product.* Potassium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6751 Sodium citrate.

(a) *Product.* Sodium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6754 Sodium diacetate.

(a) *Product.* Sodium diacetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6757 Sodium gluconate.

(a) *Product.* Sodium gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6760 Sodium hexametaphosphate.

(a) *Product.* Sodium hexametaphosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6769 Sodium metaphosphate.

(a) *Product.* Sodium metaphosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6778 Sodium phosphate.

(a) *Product.* Sodium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6787 Sodium pyrophosphate.

(a) *Product.* Sodium pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6789 Tetra sodium pyrophosphate.

(a) *Product.* Tetra sodium pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacuring practice.

§ 182.6801 Sodium tartrate.

(a) *Product.* Sodium tartrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6804 Sodium potassium tartrate.

(a) *Product.* Sodium potassium tartrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6807 Sodium thiosulfate.

(a) *Product.* Sodium thiosulfate.

(b) *Tolerance.* 0.1 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in salt in accordance with good manufacturing practice.

§ 182.6810 Sodium tripolyphosphate.

(a) *Product.* Sodium tripolyphosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6851 Stearyl citrate.

(a) *Product.* Stearyl citrate.

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 0.15 percent in accordance with good manufacturing practice.

Subpart H—Stabilizers

§ 182.7115 Agar-agar.

(a) *Product.* Agar-agar.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.7133 Ammonium alginate.

(a) *Product.* Ammonium alginate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.7187 Calcium alginate.

(a) *Product.* Calcium alginate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.7255 Chondrus extract.

(a) *Product.* Chondrus extract (carrageenin).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.7610 Potassium alginate.

(a) *Product.* Potassium alginate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.7724 Sodium alginate.

(a) *Product.* Sodium alginate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

Subpart A—General Provisions

Sec.

184.1 Substances added directly to human food affirmed as generally recognized as safe (GRAS).

Subpart B—Listing of Specific Substances Affirmed as GRAS

184.1021 Benzoic acid.
184.1271 L-Cysteine.
184.1272 L-Cysteine monohydrochloride.
184.1282 Dill and its derivatives.
184.1293 Ethyl alcohol.
184.1317 Garlic and its derivatives.
184.1330 Acacia (gum arabic).
184.1333 Gum ghatti.
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184.1343 Locust (carob) bean gum.
184.1349 Karaya gum (sterculia gum).
184.1351 Gum tragacanth.
184.1490 Methylparaben.
184.1660 Propyl gallate.
184.1670 Propylparaben.
184.1699 Oil of rue.
184.1733 Sodium benzoate.
184.1835 Sorbitol.
184.1983 Bakers yeast extract.

AUTHORITY: Secs. 409, 701, 52 Stat. 1055–1056 as amended, 72 Stat. 1785–1788 as amended (21 U.S.C. 348, 371), unless otherwise noted.

Subpart A—General Provisions

§ 184.1 Substances added directly to human food affirmed as generally recognized as safe (GRAS).

(a) The direct human food ingredients listed in this section have been reviewed by the Food and Drug Administration and determined to be generally recognized as safe (GRAS) for the purposes and under the conditions prescribed. The regulations in this section shall sufficiently describe each ingredient to identify the characteristics of the ingredient that has been affirmed as GRAS and to differentiate it from other possible versions of the ingredient that have not been affirmed as GRAS. Ingredients affirmed as GRAS in this

section may also be used as components of articles that contact food, subject to any limitations prescribed in Parts 174, 175, 176, 177, 178, or § 179.45 of this chapter or in Part 186 of this chapter.

(b) Any use levels included in this section represent maximum use levels under current good manufacturing practices. This section does not authorize addition of any level of an ingredient to a specific food above the amount reasonably necessary to accomplish the intended effect.

(1) If the ingredient is affirmed as GRAS with no limitation other than good manufacturing practice, it shall be regarded as GRAS if its conditions of use are not significantly different from those reported in the regulation as the basis on which the GRAS status of the substance was affirmed. If the conditions of use are significantly different, such use of the substance may not be GRAS. In such a case, a manufacturer may not rely on the regulation as authorizing the use but must independently establish that the use is GRAS or must use the substance in accordance with a food additive regulation.

(2) If the ingredient is affirmed as GRAS with specific limitation(s), it shall be used in food only within such limitation(s), including the category of food(s), the functional use(s) of the ingredient, and the level(s) of use. Any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation.

(3) If the ingredient is affirmed as GRAS for a specific use, without a general evaluation of use of the ingredient, other uses may also be GRAS.

(c) The listing of a food ingredient in this section does not authorize the use of such substance in a manner that may lead to deception of the consumer or to any other violation of the act.

(d) The listing of more than one ingredient to produce the same technological effect does not authorize use of a combination of two or more ingredients to accomplish the same technological effect in any one food at a combined level greater than the highest level permitted for one of the ingredients.

(e) If the Commissioner of Food and Drugs is aware of any prior sanction for use of an ingredient under conditions different from those proposed to be affirmed as GRAS, he will concurrently propose a separate regulation covering such use of the ingredient under Part 181 of this chapter. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any regulation promulgated pursuant to this section constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to the proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under Part 181 of this chapter, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

(f) The label and labeling of the ingredient and any intermediate mix of the ingredient for use in finished food shall bear, in addition to the other labeling required by the act:

(1) The name of the ingredient.

(2) A statement of concentration of the ingredient in any intermediate mix.

(3) Adequate information to assure that the final food product may comply with any limitations prescribed for the ingredient.

Subpart B—Listing of Specific Substances Affirmed as GRAS

§ 184.1021 Benzoic acid.

(a) Benzoic acid is the chemical benzenecarboxylic acid ($C_7H_6O_2$), occurring in nature in free and combined forms. Among the foods in which benzoic acid occurs naturally are cranberries, prunes, plums, cinnamon, ripe cloves, and most berries. Benzoic acid is manufactured by treating molten phthalic anhydride with steam in the presence of a zinc oxide catalyst, by the hydrolysis of benzotrichloride, or by the oxidation of toluene with nitric acid or sodium bichromate or with air in the presence of a transition metal salt catalyst.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972)[11].

(c) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter, and as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice. Current usage results in a maximum level of 0.1 percent in food. (The Food and Drug Administration has not determined whether significantly different conditions of use would be GRAS).

(e) Prior sanctions for this ingredient different from those uses established in this section, or different from that set forth in Part 181 of this chapter, do not exist or have been waived.

§ 184.1271 L-Cysteine.

(a) L-Cysteine is the chemical L-2-amino-3-mercaptopropanoic acid ($C_3H_7O_2NS$).

(b) The ingredient meets the appropriate part of the specification set forth in the Food Chemicals Codex, 2d Ed. (1972)[11] for L-cysteine monohydrochloride.

(c) The ingredient is used to supply up to 0.009 part of total L-cysteine per 100 parts of flour in dough as a dough strengthener as defined in § 170.3(o)(6) of this chapter in yeast-leavened baked goods and baking mixes as defined in § 170.3(n)(1) of this chapter.

(d) This regulation is issued prior to a general evaluation of use of this ingredient in order to affirm as GRAS the specific use named.

§ 184.1272 L-Cysteine monohydrochloride.

(a) L-Cysteine monohydrochloride is the chemical L-2-amino-3-mercaptopropanoic acid monohydrochloride monohydrate ($C_3H_7O_2NS\ HCl\ H_2O$).

(b) The ingredient meets the specifications of Food Chemicals Codex, 2d Ed. (1972).[11]

(c) The ingredient is used to supply up to 0.009 part of total L-cysteine per 100 parts of flour in dough as a dough strengthener as defined in § 170.3(o)(6) of this chapter in yeast-leavened baked goods and baking mixes as defined in § 170.3(n)(1) of this chapter.

(d) This regulation is issued prior to a general evaluation of use of this ingredient in order to affirm as GRAS the specific use named.

§ 184.1282 Dill and its derivatives.

(a) Dill (American or European) is the herb and seeds from *Anethum graveolens* L., and dill (Indian) is the herb and seeds from *Anethum sowa*, D.C. Its derivatives include essential oils, oleoresins, and natural extractives obtained from these sources of dill.

(b) Dill oils meet the description and specifications of the Food Chemicals Codex, 2d Ed. (1972).[11]

(c) Dill and its derivatives are used as flavoring agents and adjuvants as defined in § 170.3(o)(12) of this chapter.

(d) The ingredients are used in food at levels not to exceed good manufacturing practice.

(e) The requirement of § 184.1(f)(2) is optional.

(f) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

§ 184.1293 Ethyl alcohol.

(a) Ethyl alcohol (ethanol) is the chemical C_2H_5OH.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972)[11] and the formula requirements of 26 CFR Part 212.

(c) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter on pizza crusts prior to final baking at levels not to exceed 2.0 percent by product weight.

(d) This regulation is issued prior to general evaluation of use of this ingredient in order to affirm as GRAS the specific use named.

§ 184.1317 Garlic and its derivatives.

(a) Garlic is the fresh or dehydrated bulb or cloves obtained from *Allium sativum*, a genus of the lily family. Its derivatives include essential oils, oleoresins, and natural extractives obtained from garlic.

(b) Garlic oil meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).[11]

(c) Garlic and its derivatives are used as flavoring agents and adjuvants as de-

[11] Copies may be obtained from: The National Academy of Sciences, 2101 Constitution Ave. NW., Washington, D.C. 20037.

fined in § 170.3(o)(12) of this chapter.

(d) The ingredients are used in food at levels not to exceed good manufacturing practice.

(e) The requirement of § 184.1 (f)(2) is optional.

(f) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

§ 184.1330 Acacia (gum arabic).

(a) Acacia (gum arabic) is the dried gummy exudate from stems and branches of trees of various species of the genus *Acacia*, family Leguminosae.

(b) The ingredient meets specifications of the Food Chemicals Codex, 2d Ed. (1972).[11]

(c) The ingredient is used in food under the following conditions:

Maximum usage levels permitted

Food (as served)	Percent	Function
Beverages and beverage bases, sec. 170.3(n)(3) of this chapter.	2.0	Emulsifier and emulsifier salt, sec. 170.3(o)(8) of this chapter; flavoring agent and adjuvant, sec. 170.3(o)(12) of this chapter; formulation aid, sec. 170.3(o)(14) of this chapter; stabilizer and thickener, sec. 170.3(o)(28) of this chapter.
Chewing gum, sec. 170.3(n)(6) of this chapter	5.0	Flavoring agent and adjuvant, sec. 170.3(o)(12) of this chapter; formulation aid, sec. 170.3(o)(14) of this chapter; humectant, sec. 170.3(o)(16) of this chapter; surface-finishing agent, sec. 170.3(o)(30) of this chapter.
Confections and frostings, sec. 170.3(n)(9) of this chapter.	12.0	Formulation aid, sec. 170.3(o)(14) of this chapter; stabilizer and thickener, sec. 170.3(o)(28) of this chapter; surface-finishing agent, sec. 170.3(o)(30) of this chapter.
Dairy product analogs, sec. 170.3(n)(10) of this chapter.	1.0	Formulation aid, sec. 170.3(o)(14) of this chapter; stabilizer and thickener, sec. 170.3(o)(28) of this chapter.
Fats and oils, sec. 170.3(n)(12) of this chapter	1.5	Formulation aid, sec. 170.3(o)(14) of this chapter; stabilizer and thickener, sec. 170.3(o)(28) of this chapter.
Gelatins, puddings, and fillings, sec. 170.3(n)(22) of this chapter.	2.5	Emulsifier and emulsifier salt, sec. 170.3(o)(8) of this chapter; formulation aid, sec. 170.3(o)(14) of this chapter; stabilizer and thickener, sec. 170.3(o)(28) of this chapter.
Hard candy and cough drops, sec. 170.3(n)(25) of this chapter.	46.5	Flavoring agent and adjuvant, sec. 170.3(o)(12) of this chapter; formulation aid, sec. 170.3(o)(14) of this chapter.
Nuts and nut products, sec. 170.3(n)(32) of this chapter.	8.3	Formulation aid, sec. 170.3(o)(14) of this chapter; surface-finishing agent, sec. 170.3(o)(30) of this chapter.
Snack foods, sec. 170.3(n)(37) of this chapter	4.0	Emulsifier and emulsifier salt, sec. 170.3(o)(8) of this chapter; formulation aid, sec. 170.3(o)(14) of this chapter.
Soft candy, sec. 170.3(n)(38) of this chapter	85.0	Emulsifier and emulsifier salt, sec. 170.3(o)(8) of this chapter; firming agent, sec. 170.3(o)(10) of this chapter; flavoring agent and adjuvant, sec. 170.3(o)(12) of this chapter; formulation aid, sec. 170.3(o)(14) of this chapter, humectant, sec. 170.3(o)(16) of this chapter; stabilizer and thickener, sec. 170.3(o)(28) of this chapter; surface-finishing agent, sec. 170.3(o)(30) of this chapter.
All other food categories	1.0	Emulsifier and emulsifier salt, sec. 170.3(o)(8) of this chapter; flavoring agent and adjuvant, sec. 170.3(o)(12) of this chapter; formulation aid, sec. 170.3(o)(14) of this chapter; processing aid, sec. 170.3(o)(24) of this chapter; stabilizer and thickener, sec. 170.3(o)(28) of this chapter; surface-finishing agent, sec. 170.3(o)(30) of this chapter; texturizer, sec. 170.3(o)(32) of this chapter.

(d) The requirement of § 184.1(f)(2) is optional.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

§ 184.1333 Gum ghatti.

(a) Gum ghatti (Indian gum) is an exudate from wounds in the bark of *Anogeissus latifolia*, a large tree found in the dry deciduous forests of India and Ceylon.

(b) The ingredient complies with the following specifications:

(1) *Viscosity of a 1-percent solution.* Not less than the minimum or within the range claimed by the vendor.

(2) *Limits of impurities*—(i) *Arsenic (as AL).* Not more than 3 parts per million (0.0003 percent);

(ii) *Ash (acid-insoluble).* Not more than 1.75 percent;

(iii) *Ash (total).* Not more than 6.0 percent;

(iv) *Heavy metals (as Pb).* Not more than 40 parts per million (0.004 percent); and

(v) *Lead.* Not more than 10 parts per million (0.001 percent).

(3) *Loss on drying.* Not more than 14 percent dried at 105° C for 5 hours.

(4) *Identification test.* Add 0.2 ml of diluted lead subacetate (basic lead acetate, *AOAC*, 12th Ed. 1975, Section 31.164 (b))[2] to 5 ml of a cold 1-in-100 aqueous solution of the gum. An immediate, voluminous, opaque precipitate indicates acacia. A small precipitate or clear solution which produces an opaque flocculent precipitate upon the addition of 1 ml of 3*N* ammonium hydroxide indicates gum ghatti.

(c) The ingredient is used in food under the following conditions:

Maximum usage levels permitted

Food (as served)	Percent	Function
Beverages and beverage bases, nonalcoholic, sec. 170.3(n)(3) of this chapter.	0.2	Emulsifier and emulsifier salt, sec. 170.3(o)(8) of this chapter.
All other food categories	.1	Emulsifier and emulsifier salt, sec. 170.3(o)(8) of this chapter.

[11] Copies may be obtained from: The National Academy of Sciences, 2101 Constitution Ave. NW., Washington, D.C. 20037.

[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C 20044.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

§ 184.1339 Guar gum.

(a) Guar gum is the natural substance obtained from the maceration of the seed of the guar plant, *Cyamopsis tetragonoloba* (Linne) Taub., or *Cyamopsis psoraloides* (Lam.) D.C.

(b) The ingredient meets specifications of the Food Chemicals Codex, 2d Ed. (1972).[11]

(c) The ingredient is used in food under the following conditions:

Maximum usage levels permitted

Food (as served)	Percent	Function
Baked goods and baking mixes, sec. 170.3(n)(1) of this chapter.	0.35	Emulsifier and emulsifier salts, sec. 170.3(o)(8) of this chapter; formulation aid, sec. 170.3(o)(14) of this chapter; stabilizer and thickener; sec. 170.3(o)(28) of this chapter.
Breakfast cereals, sec. 170.3(n)(4) of this chapter.	1.2	Formulation aid, sec. 170.3(o)(14) of this chapter; stabilizer and thickener, sec. 170.3(o)(28) of this chapter.
Cheese, sec. 170.3(n)(5) of this chapter	.8	Do.
Dairy products analogs, sec. 170.3(n)(10) of this chapter.	1.0	Firming agent, sec. 170.3(o)(10) of this chapter; formulation aid, sec. 170.3(o)(14) of this chapter; stabilizer and thickener, sec. 170.3(o)(28) of this chapter.
Fats and oils, sec. 170.3(n)(12) of this chapter.	2.0	Do.
Gravies and sauces, sec. 170.3(n)(24) of this chapter.	1.2	Formulation aid, sec. 170.3(o)(14) of this chapter; stabilizer and thickener, sec. 170.3(o)(28) of this chapter.
Jams and jellies, commercial, sec. 170.3(n)(28) of this chapter.	1.0	Do.
Milk products, sec. 170.3(n)(31) of this chapter.	.6	Do.
Processed vegetables and vegetable juices, sec. 170.3(n)(36) of this chapter.	2.0	Formulation aid, sec. 170.3(o)(14) of this chapter; stabilizer and thickener, sec. 170.3(o)(28) of this chapter.
Soups and soup mixes, sec. 170.3(n)(40) of this chapter.	.8	Do.
Sweet sauces, toppings and syrups, sec. 170.3(n)(43) of this chapter.	1.0	Do.
All other food categories	.5	Emulsifier and emulsifier salts, sec. 170.3(o)(8) of this chapter; firming agent, sec. 170.3(o)(10) of this chapter; formulation aid, sec. 170.3(o)(14) of this chapter; stabilizer and thickener, sec. 170.3(o)(28) of this chapter.

(d) The requirement of § 184.1(f)(2) is optional.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

§ 184.1343 Locust (carob) bean gum.

(a) Locust (carob) bean gum is primarily the macerated endosperm of the seed of the locust (carob) bean tree, *Ceratonia siliqua* (Linne) a leguminous evergreen tree, with lesser quantities of seed coat and germ.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).[11]

(c) The ingredient is used at levels not to exceed the following maximum levels:

Maximum usage levels permitted

Food (as served)	Percent	Function
Baked goods and baking mixes, sec. 170.3(n)(1) of this chapter.	0.15	Stabilizer and thickener, sec. 170.3(o)(28) of this chapter.
Beverages and beverage bases, nonalcoholic, sec. 170.3(n)(3) of this chapter.	.25	Do.
Cheeses, sec. 170.3(n)(5) of this chapter	.8	Do.
Gelatins, puddings, and fillings, sec. 170.3(n)(22) of this chapter.	.75	Do.
Jams and jellies, commercial, sec. 170.3(n)(28) of this chapter.	.75	Do.
All other food categories	.5	Do.

(d) The requirement of § 184.1(f)(2) is optional.

(e) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

§ 184.1349 Karaya gum (sterculia gum).

(a) Karaya gum (sterculia gum) is the dried gummy exudate from the trunk of trees of various species of the genus *Sterculia*.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).[11]

(c) The ingredient is used in food under the following conditions:

Maximum usage levels permitted

Food (as served)	Percent	Function
Frozen dairy desserts and mixes, sec. 170.3(n)(20) of this chapter.	0.3	Formulation aid, sec. 170.3(o)(14) of this chapter; stabilizer and thickener, sec. 170.3(o)(28) of this chapter.
Milk products, sec. 170.3(n)(31) of this chapter.	.02	Stabilizer and thickener, sec. 170.3(o)(28) of this chapter.
Soft candy, sec. 170.3(n)(38) of this chapter	.9	Emulsifier and emulsifier salt, sec. 170.3(o)(8) of this chapter; stabilizer and thickener, sec. 170.3(o)(28) of this chapter.
All other food categories	.002	Formulation aid, sec. 170.3(o)(14) of this chapter; stabilizer and thickener, sec. 170.3(o)(28) of this chapter.

[11] Copies may be obtained from: The National Academy of Sciences, 2101 Constitution Ave. NW., Washington, D.C. 20037.

(d) The requirement of § 184.1(f)(2) is optional.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

§ 184.1351 Gum tragacanth.

(a) Guam tragacanth is the exudate from one of several species of *Astragalus gummifer* Labillardiere, a shrub that grows wild in mountainous regions of the Middle East.

(b) The ingredient meets the specifications of the Food and Chemicals Codex, 2d Ed. (1972) [11]

(c) The ingredient is used in food under the following conditions:

Maximum usage levels permitted

Food (as served)	Percent	Function
Baked goods and baking mixes, sec. 170.3(n)(1) of this chapter.	0.2	Emulsifier and emulsifier salt, sec. 170.3(o)(8) of this chapter; formulation aid, sec. 170.3(o)(14) of this chapter; stabilizer and thickener, sec. 170.3(o)(28) of this chapter.
Condiments and relishes, sec. 170.3(n)(8) of this chapter.	.7	Do.
Fats and oils, sec 170.3(n)(12) of this chapter	1.3	Do
Gravies and sauces, sec. 170.3(n)(24) of this chapter.	.8	Do.
Meat products, sec. 170.3(n)(29) of this chapter.	.2	Formulation aid, sec. 170.3(o)(14) of this chapter; stabilizer and thickener, sec. 170.3(o)(28) of this chapter.
Processed fruits and fruit juices, sec. 170.3(n)(35) of this chapter.	.2	Emulsifier and emulsifier salt, sec. 170.3(o)(8) of this chapter; formulation aid, sec. 170.3(o)(14) of this chapter; stabilizer and thickener, sec. 170.3(o)(28) of this chapter.
All other food categories	.1	Do.

(d) The requirement of § 184.1(f)(2) is optional.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

§ 184.1490 Methylparaben.

(a) Methylparaben is the chemical methyl *p*-hydroxybenzoate. It is produced by the methanol esterification of *p*-hydroxybenzoic acid in the presence of sulfuric acid, with subsequent distillation.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).[11]

(c) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practices. Current good manufacturing practice results in a maximum level of 0.1 percent in food.

(e) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

§ 184.1660 Propyl gallate.

(a) Propyl gallate is the *n*-propylester of 3,4,5-trihydroxybenzoic acid ($C_{10}H_{12}O_5$). Natural occurrence of propyl gallate has not been reported. It is commercially prepared by esterification of gallic acid with propyl alcohol followed by distillation to remove excess alcohol.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).[11]

(c) The ingredient is used as an antioxidant as defined in § 170.3(o)(3) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice. Current usage results in a maximum level of 0.015 percent in food. (The Food and Drug Administration has not determined whether significantly different conditions of use would be GRAS.)

(e) Prior sanctions for this ingredient different from the uses established in this section, or different from that stated in Part 181 of this chapter, do not exist or have been waived.

§ 184.1670 Propylparaben.

(a) Propylparaben is the chemical propyl *p*-hydroxybenzoate. It is produced by the *n*-propanol esterification of *p*-hydroxybenzoic acid in the presence of sulfuric acid, with subsequent distillation.

(b) The ingredient meets the specifications of the Food Chemicals Codex 2d Ed. (1972).[11]

(c) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practices. Current good manufacturing practice results in a maximum level of 0.1 percent in food.

(e) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

§ 184.1699 Oil of rue.

(a) Oil of rue is the natural substance obtained by steam distillation of the fresh blossoming plants of rue, the perennial herb of several species of *Ruta—Ruta montana* L., *Ruta graveolens* L., *Ruta bracteosa* L., and *Ruta calepensis* L.

(b) Oil of rue meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).[11]

(c) The ingredient is used in food under the following conditions:

[11] Copies may be obtained from: The National Academy of Sciences, 2101 Constitution Ave. NW., Washington, D.C. 20037.

Maximum usage levels permitted

Food (as served)	Parts per million	Function
Baked goods and baking mixes, sec. 170.3(n)(1), of this chapter.	10	Flavoring agent and adjuvant, sec. 170.3(o)(12) of this chapter.
Frozen dairy desserts and mixes, sec. 170.3(n)(20) of this chapter.	10	Do.
Soft candy, sec. 170.3(n)(38) of this chapter	10	Do.
All other food categories	4	Do.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

§ 184.1733 Sodium benzoate.

(a) Sodium benzoate is the chemical benzoate of soda ($C_7H_5NaO_2$), produced by the neutralization of benzoic acid with sodium bicarbonate, sodium carbonate, or sodium hydroxide. The salt is not found to occur naturally.

(b) The ingredient meets the specification of the Food Chemicals Codex, 2d Ed. (1972).[1]

(c) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter, and as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice. Current usage results in a maximum level of 0.1 percent in food. (The Food and Drug Administration has not determined whether significally different conditions of use would be GRAS.)

(e) Prior sanctions for this ingredient different from the uses established in this section, or different from that set forth in Part 181 of this chapter, do not exist or have been waived.

§ 184.1835 Sorbitol.

(a) Sorbitol is the chemical 1,2,3,4,5,6-hexanehexol ($C_6H_{14}O_6$), a hexahydric alcohol, differing from mannitol principally by having a different optical rotation. Sorbitol is produced by the electrolytic reduction, or the transition metal catalytic hydrogenation of sugar solutions containing glucose or fructose.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).[1]

(c) The ingredient is used as an anticaking agent and free-flow agent as defined in § 170.3(o)(1) of this chapter, curing and pickling agent as defined in § 170.3(o)(5) of this chapter, drying agent as defined in § 170.3(o)(7) of this chapter, emulsifier and emulsifier salt as defined in § 170.3(o)(8) of this chapter, firming agent as defined in § 170.3(o)(10) of this chapter, flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter, formulation aid as defined in § 170.3(o)(14) of this chapter, humectant as defined in § 170.3(o)(16) of this chapter, lubricant and release agent as defined in § 170.3(o)(18) of this chapter, nutritive sweetener as defined in § 170.3(o)(21) of this chapter, sequestrant as defined in § 170.3(o)(26) of this chapter, stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, surface-finishing agent as defined in § 170.3(o)(30) of this chapter, and texturizer as defined in § 170.3(o)(32) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practices. Current good manufacturing practice in the use of sorbitol results in a maximum level of 99 percent in hard candy and cough drops as defined in § 170.3(n)(25) of this chapter, 75 percent in chewing gum as defined in § 170.3(n)(6) of this chapter, 98 percent in soft candy as defined in § 170.3(n)(38) of this chapter, 30 percent in nonstandardized jams and jellies, commercial, as defined in § 170.3(n)(28) of this chapter, 30 percent in baked goods and baking mixes as defined in § 170.3(n)(1) of this chapter, 17 percent in frozen dairy desserts and mixes as defined in § 170.3(n)(20) of this chapter, and 12 percent in all other foods.

(e) The label and labeling of food whose reasonably foreseeable consumption may result in a daily ingestion of 50 grams of sorbitol shall bear the statement: "Excess consumption may have a laxative effect."

(f) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

§ 184.1983 Bakers yeast extract.

(a) Bakers yeast extract is the food ingredient resulting from concentration of the solubles of mechanically ruptured cells of a selected strain of yeast, *Saccharomyces cerevisiae*. It may be concentrated or dried.

(b) The ingredient meets the following specifications on a dry weight basis: Less than 0.4 part per million (ppm) arsenic, 0.13 ppm cadmium, 0.2 ppm lead, 0.05 ppm mercury, 0.09 ppm selenium, and 10 ppm zinc.

(c) The viable microbial content of the finished ingredient as a concentrate or dry material is:

(1) Less than 10,000 organisms/gram by aerobic plate count.

(2) Less than 10 yeasts and molds/gram.

(3) Negative for *Salmonella, E. coli*, coagulase positive *Staphylococci, Clostridium perfringens, Clostridium botulinum*, or any other recognized microbial pathogen or any harmful microbial toxin.

(d) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter at a level not to exceed 5 percent in food.

(e) This regulation is issued prior to general evaluation of use of this ingredient in order to affirm as GRAS the specific use named.

[1] Copies may be obtained from: The National Academy of Sciences, 2101 Constitution Ave. NW., Washington, D.C. 20037.

PART 186—INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

Subpart A—General Provisions

Sec.

186.1 Substances in food-contact surfaces affirmed as generally recognized as safe (GRAS).

Subpart B—Listing of Specific Substances Affirmed as GRAS

186.1330 Acacia (gum arabic).
186.1339 Guar gum.
186.1343 Locust (carob) bean gum.
186.1673 Pulp.

AUTHORITY: Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a)).

Subpart A—General Provisions

§ 186.1 Substances in food-contact surfaces affirmed as generally recognized as safe (GRAS).

(a) The indirect human food ingredients listed in this section have been reviewed by the Food and Drug Administration and determined to be generally recognized as safe (GRAS) for the purposes and under the conditions prescribed. The regulations in this section shall sufficiently describe each ingredient to identify the characteristics of the ingredient that has been affirmed as GRAS and to differentiate it from other possible versions of the ingredient that have not been affirmed as GRAS.

(b) This section does not authorize direct addition of any food ingredient to a food. It authorizes only the use of these ingredients as indirect ingredients of food, through migration from their immediate wrapper, container, or other food-contact surface. Any migration or use levels included in this section represent maximum levels under current good manufacturing practice.

(1) If the ingredient is affirmed as GRAS with no limitation other than good manufacturing practice, it shall be regarded as GRAS if its conditions of use are not significantly different from those reported in the regulation as the basis on which the GRAS status of the substance was affirmed. If the conditions of use are significantly different, such use of the substance may not be GRAS. In such a case, a manufacturer may not rely on the regulation as authorizing the use but must independently establish that the use is GRAS or must use the substance in accordance with a food additive regulation.

(2) If the ingredient is affirmed as GRAS with specific limitation(s), it shall be used in food-contact surfaces only within such limitation(s), including the category of food-contact surface(s), the functional use(s) of the ingredient, and the level(s) of use. Any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation.

(3) If the ingredient is affirmed as GRAS for a specific use, prior to gen-

eral evaluation of use of the ingredient, other uses may also be GRAS.

(c) The listing of a food ingredient in this section does not authorize the use of such substance for the purpose of adding the ingredient to the food through extraction from the food-contact surface.

(d) The listing of a food ingredient in this section does not authorize the use of such substance in a manner that may lead to deception of the consumer or to any other violation of the act.

(e) If the Commissioner of Food and Drugs is aware of any prior sanction for use of an ingredient under conditions different from those proposed to be affirmed as GRAS, he will concurrently propose a separate regulation covering such use of the ingredient under Part 181 of this chapter. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any regulation promulgated pursuant to this section constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to the proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under Part 181 of this chapter, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

Subpart B—Listing of Specific Substances Affirmed as GRAS

§ 186.1330 Acacia (gum arabic).

(a) Acacia (gum arabic) is the dried gummy exudate from stems and branches of trees of various species of the genus *Acacia* family Leguminosae.

(b) The ingredient meets specifications of the Food Chemicals Codex, 2d Ed. (1972).[1]

(c) The ingredient is used or intended for use as a constituent of food-packaging materials.

(d) The ingredient is used at levels not to exceed good manufacturing practice.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

§ 186.1339 Guar gum (technical grade).

(a) Guar gum, technical grade, is the natural substance obtained from maceration of the seed of the guar plant, *Cyamopsis tetragonoloba* (Linne) Taub. or *Cyamopsis psoraloides* (Lam.) D.C. containing greater quantities of seed hull and embryo than guar gum meeting the specifications of the Food Chemicals Codex, 2d Ed. (1972).[1]

[1] Copies may be obtained from: The National Academy of Sciences, 2101 Constitution Ave. NW., Washington, D.C. 20037.

(b) The technical grade gum meets the following specifications:

Galactomannans, not less than 35 percent.
Acid insoluble matter, not more than 27 percent.
Loss on drying, not more than 15 percent.
Protein, not more than 27 percent.
Ash, not more than 4.5 percent.
Arsenic (As), not more than 3 parts per million.
Heavy metals (as Pb), not more than 20 parts per million.
Lead (Pb), not more than 10 parts per million.

(c) The ingredient is used or intended for use as a constituent of food-contact surfaces.

(d) The ingredient migrates to the packaged or wrapped food at levels not to exceed good manufacturing practice.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

§ 186.1343 Locust (carob) bean gum.

(a) Locust (carob) bean gum, technical grade, is primarily the macerated endosperm of the seed of the locust (carob) bean tree, *Ceratonia siliqua* (Linne), a leguminous evergreen tree, containing greater quantities of seed hull and embryo than locust (carob) bean gum meeting the specifications of the Food Chemicals Codex, 2d Ed. (1972).[1]

(b) The technical grade gum meets the following specifications:

Galactomannans, not less than 50 percent.
Acid insoluble matter, not more than 17 percent.
Loss on drying, not more than 15 percent.
Protein, not more than 15 percent.
Ash, not more than 3 percent.
Arsenic (As), not more than 3 parts per million.
Heavy metals, not more than 20 parts per million.
Lead (Pb), not more than 10 parts per million.

(c) The ingredient is used or intended for use as a constituent of food-contact surfaces.

(d) The ingredient migrates to the packaged or wrapped food at levels not to exceed good manufacturing practices.

(e) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

§ 186.1673 Pulp.

(a) Pulp is the soft, spongy pith inside the stem of a plant such as wood, straw, sugarcane, or other natural plant sources.

(b) The ingredient is used or intended for use as a constituent of food packaging containers.

(c) The ingredient is used in paper and paperboard made by conventional paper-making processes at levels not to exceed good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

PART 189—SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

Subpart A—General Provisions

Sec.
189.1 Substances prohibited from use in human food.

Subpart B—Substances Generally Prohibited From Addition or Use as Human Food [Reserved]

Subpart C—Substances Prohibited From Direct Addition Through Food-Contact Surfaces

189.110 Calamus and its derivatives.
189.120 Cobaltous salts and its derivatives.
189.130 Coumarin.
189.135 Cyclamate and its derivatives.
189.140 Diethylpyrocarbonate (DEPC).
189.145 Dulcin.
189.155 Monochloroacetic acid.
189.165 Nordihydroguaiaretic acid (NDGA).
189.175 P-4000.
189.180 Safrole.
189.190 Thiourea.

Subpart D—Substances Prohibited From Indirect Addition to Human Food Through Food-Contact Surfaces

189.220 Flectol H.
189.250 Mercaptoimidazoline and 2-mercaptoimidazoline.
189.280 4,4'-Methylenebis (2-chloroaniline).

AUTHORITY: Secs. 409, 701, 52 Stat. 1055–1056 as amended, 72 Stat. 1785–1788 as amended (21 U.S.C. 348, 371), unless otherwise noted.

Subpart A—General Provisions

§ 189.1 Substances prohibited from use in human food.

(a) The food ingredients listed in this section have been prohibited from use in human food by the Food and Drug Administration because of a determination that they present a potential risk to the public health or have not been shown by adequate scientific data to be safe for use in human food. Use of any of these substances in violation of this section causes the food involved to be adulterated in violation of the act.

(b) This section includes only a partial list of substances prohibited from use in human food, for easy reference purposes, and is not a complete list of substances that may not lawfully be used in human food. No substance may be used in human food unless it meets all applicable requirements of the act.

(c) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish, amend, or repeal a regulation under this section on the basis of new scientific evaluation or information. Any such petition shall include an adequate scientific basis to support the petition, pursuant to Part 2 of this chapter, and will be published for comment if it contains reasonable grounds.

Subpart B—Substances Generally Prohibited from Addition or Use as Human Food [Reserved]

Subpart C—Substances Prohibited From Direct Addition or Use as Human Food

§ 189.110 Calamus and its derivatives.

(a) Calamus is the dried rhizome of *Acorus calamus* L. It has been used as a

flavoring compound, especially as the oil or extract.

(b) Food containing any added calamus, oil of calamus, or extract of calamus is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of May 9, 1968 (33 FR 6967).

(c) The analytical method used for detecting oil of calamus (β-asarone) is in the *Journal of the Association of Official Analytical Chemists* 56(5):1281–1283, Sept. 1973.[1]

§ 189.120 Cobaltous salts and its derivatives.

(a) Cobaltous salts are the chemicals, $CoC_4H_6O_4$, $CoCl_2$, and $CoSO_4$. They have been used in fermented malt beverages as a foam stabilizer and to prevent "gushing."

(b) Food containing any added cobaltous salts is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of August 12, 1966 (31 FR 8788).

§ 189.130 Coumarin.

(a) Coumarin is the chemical 1,2-benzopyrone, $C_9H_6O_2$. It is found in tonka beans and extract of tonka beans, among other natural sources, and is also synthesized. It has been used as a flavoring compound.

(b) Food containing any added coumarin as such or as a constituent of tonka beans or tonka extract is deemed to be adulterated under the act, based upon an order published in the FEDERAL REGISTER of March 5, 1953 (19 FR 1239).

(c) The analytical methods used for detecting coumarin in food are in §§ 19.014 through 19.023 of the "Official Methods of Analysis of the Association of Official Analytical Chemists."[2]

§ 189.135 Cyclamate and its derivatives.

(a) Calcium, sodium, magnesium and potassium salts of cyclohexane sulfamic acid, $(C_6H_{12}NO_3S)_2Ca$, $(C_6H_{12}NO_3S)Na$, $(C_6H_{12}NO_3S)_2Mg$, and $(C_6H_{12}NO_3S)K$. Cyclamates are synthetic chemicals having a sweet taste 30 to 40 times that of sucrose, are not found in natural products at levels detectable by the official methodology, and have been used as artificial sweeteners.

(b) Food containing any added or detectable level of cyclamate is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of October 21, 1969 (34 FR 17063).

(c) The analytical methods used for detecting cyclamate in food are in §§ 20.127 through 20.132 of the "Official Methods of Analysis of the Association of Official Analytical Chemists."[2]

§ 189.140 Diethylpyrocarbonate (DEPC).

(a) Diethylpyrocarbonate is the chemical pyrocarbonic acid diethyl ester, $C_6H_{10}O_5$. It is a synthetic chemical not found in natural products at levels detectable by available methodology and has been used as a ferment inhibitor in alcoholic and nonalcoholic beverages.

(b) Food containing any added or detectable level of DEPC is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of August 2, 1972 (37 FR 15426).

§ 189.145 Dulcin.

(a) Dulcin is the chemical 4-ethoxyphenylurea, $C_9H_{12}N_2O_2$. It is a synthetic chemical having a sweet taste about 250 times that of sucrose, is not found in natural products at levels detectable by the official methodology, and has been proposed for use as an artificial sweetener.

(b) Food containing any added or detectable level of dulcin is deemed to be adulterated in violation of the act, based upon an order published in the FEDERAL REGISTER of January 19, 1950 (15 FR 321).

(c) The analytical methods used for detecting dulcin in food are in §§ 20.133 through 20.136 of the "Official Methods of Analysis of the Association of Official Analytical Chemists."[2]

§ 189.155 Monochloroacetic acid.

(a) Monochloroacetic acid is the chemical chloroacetic acid, $C_2H_3ClO_2$. It is a synthetic chemical not found in natural products, and has been proposed as a preservative in alcoholic and nonalcoholic beverages. Monochloracetic acid is permitted in food package adhesives with an accepted migration level up to 10 parts per billion (ppb) under § 175.105 of this chapter. The official methods do not detect monochloroacetic acid at the 10 ppb level.

(b) Food containing any added or detectable level of monochloroacetic acid is deemed to be adulterated in violation of the act based upon trade correspondence dated December 29, 1941 (TC–377).

(c) The analytical methods used for detecting monochloroacetic acid in food are in §§ 20.057 through 20.062 of the "Official Methods of Analysis of the Association of Official Analytical Chemists."[2]

§ 189.165 Nordihydroguaiaretic acid (NDGA).

(a) Nordihydroguaiaretic acid is the chemical 4,4'-(2,3-dimethyltetramethylene)dipyrocatechol. $C_{18}H_{22}O_4$. It occurs naturally in the resinous exudates of certain plants. The commercial product, which is synthesized, has been used as an antioxidant in foods.

(b) Food containing any added NDGA is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of April 11, 1968 (33 FR 5619).

(c) The analytical method used for detecting NDGA in food is in § 20.008 of the "Official Methods of Analysis of the Association of Official Analytical Chemists."[2]

§ 189.175 P–4000.

(a) P–4000 is the chemical 5-nitro-2-n-propoxyaniline, $C_9H_{12}N_2O_3$. It is a synthetic chemical having a sweet taste about 4000 times that of sucrose, is not found in natural products at levels detectable by the official methodology, and has been proposed for use as an artificial sweetener.

(b) Food containing any added or detectable level of P–4000 is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of January 19, 1950 (15 FR 321).

(c) The analytical methods used for detecting P–4000 in food are in §§ 20.137 through 20.141 of the "Official Methods of Analysis of the Association of Official Analytical Chemists."[2]

§ 189.180 Safrole.

(a) Safrole is the chemical 4-allyl-1,2-methylenedioxy-benzene, $C_{10}H_{10}O_2$. It is a natural constituent of the sassafras plant. Oil of sassafras is about 80 percent safrole. Isosafrole and dihydrosafrole are derivatives of safrole, and have been used as flavoring compounds.

(b) Food containing any added safrole, oil of sassafras, isosafrole, or dihydrosafrole, or any safrole as a constituent of any food or extract is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of December 3, 1960 (25 FR 12412).

(c) The analytical method used for detecting safrole, isosafrole and dihydrosafrole is in the *Journal of the Association of Official Analytical Chemists* 54(4):900–902, July 1971.[2]

§ 189.190 Thiourea.

(a) Thiourea is the chemical thiocarbamide, CH_4N_2S. It is a synthetic chemical, is not found in natural products at levels detectable by the official methodology, and has been proposed as an antimycotic for use in dipping citrus.

(b) Food containing any added or detectable level of thiourea is deemed to be adulterated under the act.

(c) The analytical methods used for detecting thiourea are in §§ 20.009 through 20.100 of the "Official Methods of Analysis of the Association of Official Analytical Chemists."[2]

Subpart D—Substances Prohibited From Indirect Addition to Human Food Through Food-Contact Surfaces

§ 189.220 Flectol H.

(a) Flectol H is the chemical 1,2-dihydro-2,2,4-trimethylquinoline, polymerized, $C_{12}H_{17}N$. It is a synthetic chemical not found in natural products, and has been used as a component of food packaging adhesives.

(b) Food containing any added or detectable level of this substance is deemed

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[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

[1] "Collaborative Study of the Determination of Soluble Solids in Tomato Products by Refractive Index Expressed as Percent Sucrose" by Frank C. Lamb, National Canners Association, 1950 Sixth Street, Berkeley, CA 94710, "Journal of the Association of Official Analytical Chemists," vol. 52, No. 5 (1969), pp. 1050–54. Adopted as official, first action at the 1969 AOAC meeting.

to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of April 7, 1967 (32 FR 5675).

§ 189.250 Mercaptoimidazoline and 2-mercaptoimidazoline.

(a) Mercaptoimidazoline and 2-mercaptoimidazoline both have the molecular formula $C_3H_6N_2S$. They are synthetic chemicals not found in natural products and have been used in the production of rubber articles that may come into contact with food.

(b) Food containing any added or detectable levels of these substances is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of November 30, 1973 (38 FR 33072).

§ 189.280 4,4'-Methylenebis (2-chloroanaline).

(a) 4,4'-Methylenebis (2-chloroanaline) has the molecular formula, $C_{13}H_{12}Cl_2N_2$. It is a synthetic chemical not found in natural products and has been used as a polyurethane curing agent and as a component of food packaging adhesives and polyurethane resins.

(b) Food containing any added or detectable level of this substance is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of December 2, 1969 (34 FR 19073).

PART 197—SEAFOOD INSPECTION PROGRAM

Subparts A, B, C—[Reserved]

Subpart D—Inspection of Canned Oysters

Sec.

197.310 Application for inspection service.
197.312 Granting or refusing inspection service; cancellation of application.
197.315 Suspension and withdrawal of inspection service.
197.320 Inspection periods.
197.325 Assignment of inspectors.
197.329 Uninspected oysters excluded from inspected establishments.
197.330 General requirements for plant and equipment.
197.340 General operating conditions.
197.350 Code marking.
197.355 Processing.
197.360 Examination after canning.
197.370 Labeling.
197.380 Certificates of inspection; warehousing and export permits.
197.385 Inspection fees.

Subparts E, F, G, H—[Reserved]

Subpart I—Inspection of Processed Shrimp

197.810 Application for inspection service.
197.812 Granting or refusing inspection service; cancellation of application.
197.815 Suspension and withdrawal of inspection service.
197.820 Inspection periods.
197.825 Assignment of inspectors.
197.829 Uninspected shrimp excluded from inspected establishments.
197.830 General requirements for plant and equipment.
197.840 General operating conditions.
197.850 Code marking.
197.855 Processing.
197.860 Examination after processing.
197.870 Labeling.
197.880 Certificates of inspection; warehousing and export permits.
197.885 Inspection fees.

AUTHORITY: The provisions of this Part 197 issued under sec. 701, 52 Stat. 1055–1056 as amended (21 U.S.C. 371).

Subparts A, B, C—[Reserved]

Subpart D—Inspection of Canned Oysters

§ 197.310 Application for inspection service.

(a) Applications for inspection service on canned oysters under the provisions of section 702a of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372a) shall be on forms supplied by the Food and Drug Administration. No application for a regular inspection period filed with the Food and Drug Administration after September 1 preceding such period in any year shall be considered unless the applicant shows substantial cause for failure to file such application on or before September 1 of such year. The opening date of the canning season in each State shall be the date set by the State agency responsible for controlling the opening date of the canning season in that State. A separate application shall be made for each inspection period in each establishment for which the service is applied. Each application for a regular inspection period shall be accompanied by a payment of $600.00 as prescribed by § 197.385 (a) (1). Such deposit shall be paid in the manner prescribed by § 197.385 (e).

(b) For the purpose of §§ 197.310 through 197.385, an establishment is defined as a factory where oysters may be processed and warehouses under the control and direction of the packer where such canned oysters are stored.

§ 197.312 Granting or refusing inspection service; cancellation of application.

(a) The Secretary of Health, Education, and Welfare may grant the inspection service applied for upon determining that the establishment covered by such application complies with the requirements of § 197.330.

(b) The Secretary may refuse to grant the inspection service at any establishment for cause. In case of refusal the applicant shall be notified of the reason therefor and shall have returned to him all advance payments and production deposits made, less any expenses incurred for preliminary inspection of the establishment, or for other purposes incident to such application.

(c) The applicant, by written notice to the Secretary, may withdraw his application for inspection service before an inspector is assigned to the establishment. In case of such withdrawal, the Secretary shall return to such applicant all advance payments and production deposits made, less any salary and other expense incurred incident to such application.

§ 197.315 Suspension and withdrawal of inspection service.

(a) The Administration may suspend and the Secretary may withdraw inspection service in any establishment upon failure of the packer to comply with any applicable provision of §§ 197.310 through 197.385 or upon the dissemination by the packer or any person in privity with him of any representation that is false or misleading in any particular regarding the application to any seafood of the inspection service provided by the regulations in this part.

(b) When inspection service is suspended in an establishment, as authorized by paragraph (a) of this section, the Food and Drug Administration shall not lengthen the inspection period in such establishment to compensate for any of the time of suspension.

§ 197.320 Inspection periods.

(a) The regular inspection period in each establishment in which inspection service under §§ 197.310 through 197.385 is granted consists of 4 consecutive months. The date of the beginning of such regular inspection period shall be regarded as the date, on or after October 1 but not later than March 1, specified for the beginning of the service in the application therefor, or such other date as may be specified by amendment to such application and approved; but if the Secretary is not prepared to begin the service on the specified date then the period shall start on the date on which service is begun.

(b) Extension inspection periods shall begin at the close of the preceding inspection period. Extension inspection periods may be granted for periods of 1 month and/or fractional parts of 1 month, but in no case less than 1 day. Extension inspection periods for 1 month may be granted in such establishment if application therefor, accompanied by a payment of $600.00, as prescribed by § 197.385(a)(3), is made at least 2 weeks in advance of the close of such preceding inspection period. Applications for extension inspection periods for fractional parts of a month may be accepted when accompanied by the payment prescribed by § 197.385(a)(3) for such extensions. No regular or extension inspection period shall extend beyond June 30 of any year.

(c) Upon request of the packer, and with the approval of the Food and Drug Administration, such service during any inspection period may be transferred from one establishment to another to be operated by the same packer; but such transfer shall not serve to lengthen any inspection period or to take the place of an extension inspection period. In case of such transfer the packer shall furnish all necessary transportation of inspectors.

(d) The inspection service shall be continuous throughout the inspection period.

§ 197.325 Assignment of inspectors.

(a) An initial assignment of at least one inspector shall be made to each establishment in which inspection service under §§ 197.310 through 197.385 is granted. Thereafter, the Food and Drug Administration shall adjust the number of inspectors assigned to each establishment and tour of duty of each inspector

to the requirements for continuous and efficient inspection.

(b) Any inspector of the Food and Drug Administration shall have free access at all times to all parts of the establishment and to all fishing and freight boats and other conveyances dredging oysters for or transporting oysters to such establishments.

§ 197.329 Uninspected oysters excluded from inspected establishments.

(a) No establishment to which inspection service on canned oysters has been granted shall at any time thereafter can oysters that have not been so inspected, or handle or store in such establishment any canned oysters that have not been so inspected; but this paragraph shall not apply to an establishment after termination of inspection service therein, or withdrawal therefrom as authorized by § 197.315.

(b) All oysters delivered to or held in an inspected establishment may be subject to inspection, but certificates of inspection shall be issued under § 197.380 only on canned oysters.

§ 197.330 General requirements for plant and equipment.

(a) All exterior openings of the cannery, including those of the shucking sheds, shall be adequately screened, and roofs and exterior walls shall be tight. When necessary, fly traps, fans, blowers, or other approved insect-control devices shall be installed.

(b) Shucking sheds and packing rooms shall be separate, and fixtures and equipment shall be so constructed and arranged as to permit thorough cleaning. Such sheds and rooms shall be adequately lighted and ventilated, and the floors shall be tight and arranged for thorough cleaning and proper drainage. Open drains from shucking shed shall not enter packing room. If shucking shed and packing room are in separate buildings, such buildings shall be not more than 100 yards apart, unless adequate provisions are made to enable efficient inspection.

(c) All surfaces of washers, tanks, belts, tables, flumes, utensils, and other equipment with which unshucked or shucked oysters come in contact after delivery to the establishment shall be of metal or of other smooth nonporous and easily cleanable material, provided such materials are not lead or other toxic substances. Metal seams shall be smoothly soldered or smoothly welded. Shucking tables shall be so constructed as to preclude contamination of working surfaces or products thereon from foot traffic or wheelbarrows or other containers used in delivering steamed oysters to such tables.

(d) Adequate supplies of suitable detergents and sanitizing agents approved by the Food and Drug Administration; clean, unpolluted running water; and steam shall be provided for washing, cleaning, and otherwise maintaining the establishment in a sanitary condition.

(e) Adequate toilet facilities of sanitary type which comply fully with applicable State laws and local ordinances shall be provided.

(f) An adequate number of sanitary washbasins, with liquid or powdered soap, shall be provided in both the shucking shed and the packing room. Paper towels shall be provided in the packing room.

(g) Signs requiring employees handling oysters to wash their hands after each absence from post of duty shall be conspicuously posted in the shucking shed and packing room and elsewhere about the premises as conditions require.

(h) One or more suitable washing devices and one or more suitable inspection belts shall be installed for the washing and subsequent inspection of the oysters before delivery for steaming or other means of opening.

(i) If steam boxes are used for opening the oysters, they shall be provided with adequate steam inlets, exhausts, drains, a safety valve, and a pressure gauge.

(j) Suitable means shall be provided for removing shells and debris from shucking shed.

(k) One or more suitable devices shall be provided for removing shell and grit from shucked oysters, for washing such oysters, and for their subsequent drainage.

(l) One or more suitable inspection belts shall be installed for the inspection of shucked oysters.

(m) Equipment shall be provided for code-marking cans.

(n) An automatic container-counting device shall be installed in each cannery line.

(o) Each sterilizing retort shall be fitted with at least the following equipment:

(1) An automatic control for regulating temperatures.

(2) An indicating mercury thermometer of a range from 170° F to 270° F, with scale divisions not greater than 2° F, installed either within a fitting attached to the shell of the retort or within the door or shell of the retort. If the thermometer is installed within a fitting, such fitting shall communicate with the chamber of the retort through an opening at least 1 inch in diameter. Such fitting shall be equipped with a bleeder at least one-eighth inch in diameter. If the thermometer is installed within the door or shell of the retort, the bulb shall project at least two-thirds of its length into the principal chamber.

(3) A recording thermometer of a range from 170° F to 270° F, with scale divisions not greater than 2° F. The bulb of such thermometer shall be installed as prescribed for the indicating mercury thermometer. The case which houses the charts and recording mechanism shall be provided with an approved lock, all keys to which shall be in the sole custody of the inspector.

(4) A pressure gauge of a range from 0 to 30 pounds, with scale divisions not greater than 1 pound and diameter of not less than 5 inches. Such gauge shall be connected to the chamber of the retort by a short gooseneck tube. The gauge shall be not more than 4 inches higher than the gooseneck.

(5) A blow-off vent of at least ¾-inch inside diameter in the top of the retort.

(6) A ⅛-inch bleeder in top of the retort.

(p) Suitable space and facilities shall be provided for the inspector to prepare records and examine samples and for the safekeeping of records and equipment.

§ 197.340 General operating conditions.

(a) The decks and holds of all boats tonging or dredging oysters for or transporting oysters to an inspected establishment, and the bodies of other conveyances so transporting oysters shall be kept in a sanitary condition. Such boats shall be equipped with adequate means for protecting the oysters against contamination with bilge water.

(b) Inspected establishments, freight boats, and other conveyances serving such establishments shall accept only live, clean, sound oysters taken from unpolluted areas. When necessary, ice or other suitable refrigeration shall be provided to prevent spoilage.

(c) After delivery of each load of oysters to the establishment, decks and holds of each boat and the body of each other conveyance or container making such delivery shall be washed down with clean, unpolluted water, and all debris shall be cleaned therefrom before such boat or other conveyance or container leaves the establishment premises.

(d) Before being steamed or opened by other means, the oysters shall be washed with clean, unpolluted water and then passed over the inspection belt and culled to remove dirty, muddy, dead, or decomposed oysters and extraneous material. Muddy oysters may be returned to the washer for rewashing.

(e) As often as is necessary to maintain sanitary conditions, unloading platforms and equipment shall be washed with clean, unpolluted water, and all debris shall be cleaned therefrom.

(f) Shells shall be removed from the shucking shed continuously.

(g) Offal, debris, or refuse from any source whatever shall not be allowed to accumulate in the cannery or, except for shells, about the premises. Shells shall not be allowed to accumulate about the premises in such a manner as to create a nuisance.

(h) The delivery of steamed oysters to shuckers by means of manually rolling, trundling, or wheelbarrowing such oysters on or above shucking tables will not be permitted.

(i) Shucking knives and shucking cups shall be thoroughly washed with soap and water and chlorinated before use each day. Chlorine solution shall be maintained at a strength of 200 parts per million.

(j) No shucked oysters shall be returned to shucker after delivery to the weigher. Shucking cups shall be cleaned

and sanitized after each delivery to the weigher.

(k) Shucked oysters being transported from one building to another shall be properly covered and protected against contamination.

(l) The shucked oysters shall be washed, separated from the shell and grit by suitable devices, and then immediately drained. The time of washing shall not exceed the minimum time necessary for cleansing.

(m) From the time of delivery to the cannery up to the time of final processing, oysters shall be handled expeditiously and under such conditions as to prevent contamination or spoilage.

(n) The packer shall destroy for food purposes under the immediate supervision of the inspector all oysters in his possession condemned by the inspector as filthy, decomposed, putrid, or unfit for food. Oysters condemned on the boat or on the unloading platfrom shall not be taken into the cannery, but shall be either destroyed or returned to a bedding ground.

(o) All portions of the establishment shall be adequately lighted to enable the inspector to perform his duties properly.

(p) All floors and other parts of the establishment including unloading platforms, and all fixtures, equipment, and utensils shall be cleaned as often as may be necessary to maintain them in a sanitary condition.

(q) The packer shall require all employees handling oysters to wash their hands after each absence from post of duty and to observe other proper habits of cleanliness.

(r) The packer shall not knowingly employ in or about the establishment any person afflicted with an infestious or contagious disease or with any open sores on exposed portions of the body.

§ 197.350 Code marking.

(a) Code marks shall be affixed to all cans and other immediate containers before they are placed in the processing retorts. Sudh marks shall show at least:

(1) The date of packing;

(2) The establishment where packed;

(3) The conveyance; and

(4) The size of the oysters when such oysters are graded for size.

(b) Keys to all code marks shall be given to the inspector.

(c) Each lot shall be stored separately pending final inspection, with a space of not less than 6 inches between stacks of each lot. For the purposes of the regulations in this part all cans or other containers bearing the same code marks shall be regarded as comprising a lot.

§ 197.355 Processing.

(a) The closure of the can or other immediate container and the time and temperature of sterilizing the canned oysters shall be adequate to prevent bacterial spoilage.

(b) The following times and temperatures shall be the minimum employed for the containers indicated:

Canned oysters

Size	Initial temperature (degrees Fahrenheit)	Time at 240° F	Time at 250° F
		Minutes	*Minutes*
211 by 212	70	24	14
211 by 300	130	23	13
211 by 304			
211 by 400			
307 by 400	70	28	14
307 by 409	130	27	13

For the purposes of this section, initial temperature is defined as the average temperature of the contents of the container at the moment steam is admitted to the sterilizing retort.

(c) The blow-off vent shall be open during the coming-up period until the mercury thermometer registers at least 215° F. Bleeders shall emit steam during the entire cooking period.

(d) The inspector shall identify each record on the thermometer chart with the code mark of the lot to which such record relates and the date of such record. The Food and Drug Administration shall keep such charts for at least 5 years, and upon request shall make them available to the packer.

(e) The packer shall keep for at least 2 years all shipping records covering shipments from each lot, and upon request shall furnish such records to any inspector of the Food and Drug Administration.

§ 197.360 Examination after canning.

(a) Adequate samples shall be drawn by the inspector from each lot of canned oysters and shall be examined to determine whether or not such canned oysters conform to all requirements of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder.

(b) The packer shall destroy for food purposes, under the immediate supervision of the inspector, all canned oysters condemned by the inspector as not complying with § 197.355, or as filthy, decomposed, putrid, or otherwise unfit for food.

§ 197.370 Labeling.

(a) Labels on canned oysters packed and certified under §§ 197.310 through 197.385 may bear the mark "Production Supervised by the U.S. Food and Drug Administration." Such mark, if used, shall be plainly and conspicuously displayed, in type of uniform size and style, on a strongly contrasting, uniform background.

(b) Two proofs, or one proof and one photostat thereof, or eight specimens of all labeling intended for use on inspected canned oysters or on or within the cases therefor shall be submitted to the Food and Drug Administration for approval. If the proofs or photostat and proof are submitted, eight specimens of the labeling shall be sent to the Food and Drug Administration after printing. The Food and Drug Administration is hereby authorized to approve labeling for use on canned oysters inspected under §§ 197.310 through 197.385. Approval shall be subject to the condition that such labeling shall be so used as to comply with the provisions of the Federal Food, Drug and Cosmetic Act, amendments thereto, and regulations thereunder. The Food and Drug Administration is also authorized to revoke any such approval for cause. The Food and Drug Administration shall not approve labeling for canned oysters intended for export under the provisions of § 197.380(e).

(c) No commercial brand or brand name appearing on labeling approved as authorized under paragraph (b) of this section and bearing the mark described in paragraph (a) of this section, and no labeling simulating any such approved labeling, shall be used after such approval on canned oysters other than those that have been handled, prepared, and packed in compliance with all provisions of §§ 197.310 through 197.385; but this section shall not apply to any packer's labeling not bearing such mark after termination of inspection or withdrawal thereof as authorized by § 197.315 or to any distributor's labeling not bearing such mark after written notice by the owner thereof to the Food and Drug Administration that the use of such labeling on inspected canned oysters has been discontinued and will not be resumed.

(d) Canned-oyster labeling authorized by paragraph (a) of this section or approved under paragraph (b) of this section shall be used only as authorized by §§ 197.310 through 197.385. Unauthorized use of such labeling renders the user liable to the penalties prescribed by the Food, Drug, and Cosmetic Act, as amended.

§ 197.380 Certificates of inspection: warehousing and export permits.

(a) After finding that the canned oysters comprising any parcel have been handled, prepared, and packed in compliance with all provisions of §§ 197.310 through 197.385; bear labeling approved as authorized under § 197.370(b); and comply with all the provisions of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder, the inspector shall issue a certificate showing that such canned oysters so comply. The certificate shall specify the code marks to which it applies, the quantity of the parcel so marked, the place where such parcel is stored, the size and kind of containers, the commercial brand name on the labels, the condition of the oysters if they are broken or if they are substandard in fill, and the destination of the lot if known. Such certificate shall become void if such labeling is removed, altered, obliterated, or replaced; but such canned oysters may be relabeled under supervision of an inspector and recertified if the inspector finds that, after being relabeled, they comply with the requirements laid down by this paragraph for the issuance of a certificate.

(b) Unless covered by certificate, canned oysters shall be moved from an inspected establishment only for storage authorized under paragraph (c) of this section, or for export authorized under paragraph (e) of this section, or for destruction as provided by § 197.360(b).

(c) Applications to move unlabeled canned oysters for storage in a warehouse elsewhere than in the establishment where such oysters were packed shall be on forms supplied by the Administration. The application shall give the name and location of the warehouse in which such canned oysters are to be stored, and shall be accompanied by an agreement signed by the operator of such warehouse that inspectors shall have free access at all times to all canned oysters so stored, and that conditions which will preserve the identity of each parcel of such canned oysters shall be continuously maintained pending issuance of a certificate thereon or removal as authorized by paragraph (d) of this section. If such application is approved and it appears to the inspector that the canned oysters comprising any parcel have been packed in compliance with §§ 197.310 through 197.385 and conform, except for the absence of labeling, to all requirements of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder, the inspector shall issue to the applicant, on his request, a warehousing permit covering such canned oysters. Such permit shall specify the code marks to which it applies, the quantity of the parcel so marked, the place from and to which such parcel is to be moved, the size of the oysters, the size and kind of containers, and the condition of the oysters if they are broken or if they are substandard in fill and, if such be the case, that they are intended for export under paragraph (e) of this section. When any provision of the agreement is violated, the Food and Drug Administration may revoke any permit issued pursuant to such agreement, and may also revoke its approval of the application for warehousing which accompanied such agreement.

(d) Unless covered by certificate, canned oysters stored under the authority of paragraph (c) of this section shall be moved from the warehouse where stored only for re-storage under such authority, or for return upon written permission of the inspector to the establishment where packed, or for export authorized under paragraph (e) of this section, or for destruction as provided by § 197.360(b).

(e) An application to export canned oysters under the provisions of section 801(d) of the act shall be accompanied by the original or a verified copy of the specifications of the foreign purchaser; if required by the Food and Drug Administration, evidence showing that such canned oysters are not in conflict with the laws of the country to which they are intended for export; and, if shipment of labeled canned oysters is specified or directed, eight specimens of the labeling therefor. If canned oysters prepared or packed according to such specifications are not in conflict with the laws of such country, the Administration shall direct the inspector to issue to the applicant an export permit covering such canned oysters comprising any parcel ordered by such purchaser under such specifications, when the inspector finds that such canned oysters were packed in compliance with the requirements of §§ 197.310 through 197.385 regarding sanitary conditions and processing; are not filthy, decomposed, putrid, or otherwise unfit for food; accord to such specifications, and are labeled on the outside of the shipping package to show that they are intended for export. Such permit shall specify the code marks to which it applies and the quantity of the parcel so marked, and shall show that such canned oysters were packed under sanitary conditions, are wholesome, and accord to such specifications. The applicant shall furnish to the inspector documentary evidence showing the exportation of all such canned oysters.

§ 197.385 Inspection fees.

(a) (1) Except as otherwise provided by the regulations in this part, an initial payment of $600.00 shall accompany each application; thereafter, three additional advance payments of $600.00 each shall be made, as follows: One payment on or before the date of the beginning of the regular inspection period specified in the application for inspection; the remaining two payments on or before the first day of each succeeding month, except that the Food and Drug Administration may require the full amount of all advance payments prescribed by this paragraph to accompany the application of an applicant who has defaulted in any payment due for any prior packing season: *Provided*, That a packer who is concurrently receiving inspection service and making payments under the regulations for the inspection of processed shrimp shall not make any additional payments under this subparagraph.

(2) Whenever it is determined, without hearing, by the Food and Drug Administration that an establishment having the inspection service has been damaged by wind, fire, flood, or other calamity to such an extent that packing operations cannot be resumed before the end of the fiscal year then current, no advance payments falling due after such calamity shall be required from the packer for that fiscal year; but whenever it is determined, without hearing, by the Food and Drug Administration that an establishment having the inspection service has been so damaged by any such calamity that operations must be suspended temporarily, but can be resumed before the end of the fiscal year then current, advance payments falling due after such calamity and before the month of resumption of operations shall be postponed until operations are resumed, and thereupon shall be paid in equal monthly installments during the period between the time of resumption of operations and June 1 of the fiscal year then current: *Provided*, That in the event of a determination described in this subparagraph the total payments and production deposits made by the packer involved shall be charged with the cost of the service made available for the establishment, without regard to the method provided hereinafter for computing charges against payments and production deposits, and the balance of the total payments and deposits remaining after such charges shall be refunded by the Food and Drug Administration to the packer after the completion of the fiscal year.

(3) Each application for an extension inspection period of 1 month shall be accompanied by a payment of $600.00, and at subsequent monthly intervals thereafter additional payments of $600.00 shall be made; but if the final payment is to cover a period of less than 30 days, then such payment shall be at the rate of $20.00 for each day of such period.

(b) (1) In addition to the payments prescribed in paragraph (a) of this section, advance deposits based upon the quantity of oysters canned by the subscribing establishment shall be made to underwrite adequately the cost of the inspection service. Such deposits shall be paid in advance in amounts of not less than $300.00, unless the Food and Drug Administration on an estimate of production authorizes other amounts, and shall be computed at the rate of 15 cents for each case of 48 cans, size 211 x 300. Any advance production deposits in excess of those required for actual oysters canned for the fiscal year (July 1 through June 30) will be refunded to the packers by the Food and Drug Administration after the completion of the fiscal year.

(2) Production deposits as computed under paragraph (b)(1) of this section, together with deposits for shrimp received as prescribed under § 197.885(b)(1), in the case of processed shrimp, shall be charged with the balance of the total cost of the inspection service which has not been provided for by the combined total payments under paragraph (a) of this section and paragraph (a) of § 197.885, in the case of processed shrimp. The balance of the production deposits remaining after such charges have been made shall be refunded by the Administration to the packers after the completion of the fiscal year in the ratio which each packer's production deposits for oysters canned and deposits for shrimp received bears to the combined total of such deposits for oysters canned and shrimp received by all packers for the fiscal year.

(3) When inspection service is withdrawn from an establishment as authorized under § 197.315(a), the Food and Drug Administration shall not return to the packer any advance payments and/or deposits required to the date of withdrawal of the service. Such payments and/or deposits shall be charged with the cost of the service made available for the establishment, without regard to the method described in this section, and the

balance that would have accrued to such packer shall remain to the credit of the Food and Drug Administration in the special account "Salaries and Expenses, Certification and Inspection Services."

(c) A separate fee shall be paid to cover all expenses incurred in accordance with the regulations of the United States Government, for salary, travel, subsistence, and for other purposes incident to inspection for the purpose of issuing a certificate or warehousing or export permit on canned oysters stored or held at any place other than an establishment to which a seafood inspector is then assigned.

(d) When the cannery and the cannery warehouse of an establishment are located at different points of such distance apart that transportation between them is required for the inspector to perform his duties in the establishment, the packer shall furnish such transportation or shall pay a separate fee to cover all expenses therefor.

(e) All payments required by the regulations in this part shall be by bank draft or certified check, collectible at par drawn to the order of the Food and Drug Administration, and payable at Washington, DC. All such drafts and checks except those for the payment required by § 197.310(a), shall be delivered to the inspector and promptly scheduled to the Food and Drug Administration, Department of Health, Education, and Welfare, Washington, DC, whereupon after appropriate records thereof have been made they shall be transmitted to the Chief Disbursing Officer, Division of Disbursement, Treasury Department, for deposit to the special account "Certification and Inspection Services, Food and Drug Administration."

(f) All refunds to packers shall be by check drawn on the Treasury of the United States pursuant to refund vouchers duly certified and approved by the designated administrative officers.

Subparts E, F, G, H—[Reserved]

Subpart I—Inspection of Processed Shrimp

§ 197.810 Application for inspection service.

(a) Applications for inspection service on the processing of shrimp under the provisions of section 702a of the Federal Food, Drug, and Cosmetic Act shall be on forms supplied by the Food and Drug Administration. The processing of shrimp comprises all the operations including labeling and storage, necessary to prepare for the market shrimp in any of the following forms: Iced or frozen raw headless, raw peeled or cooked peeled (any of which may be deveined); iced or frozen deveined shrimp, partially or completely peeled (which may be battered and breaded before freezing), and canned shrimp. No application for a regular inspection period filed with the Food and Drug Administration after May 1, preceding such period in any year, shall be considered unless the applicant shows substantial cause for failure to file such application on or before May 1 of such year. A separate application shall be made for each inspection period in each establishment for which the service is applied. Each application for a regular inspection period shall be accompanied by an advance payment of $500.00 as prescribed by § 197.885(a)(1). Such payment shall be made in the manner prescribed by § 197.885(e).

(b) For the purposes of §§ 197.810 through 197.885, an establishment is defined as a factory where shrimp may be processed and warehouses and cold storage plants under the control and direction of the packer where such shrimp is stored.

§ 197.812 Granting or refusing inspection service; cancellation of application.

(a) The Secretary of Health, Education, and Welfare may grant the inspection service applied for upon determining that the establishment covered by such application complies with the requirements of § 197.830.

(b) The Secretary may refuse to grant inspection service at any establishment for cause. In case of refusal, the applicant shall be notified of the reason therefor and shall have returned all advance payments and deposits made, less any expenses incurred for preliminary inspection of the establishment or for other purposes incident to such application.

(c) The applicant, by written notice to the Secretary, may withdraw his application for inspection service before July 1 preceding the inspection period covered by the application. In case of such withdrawal, the Secretary shall return to such applicant all advance payments and deposits made, less any salary and other expense incurred incident to such application.

§ 197.815 Suspension and withdrawal of inspection service.

(a) The Food and Drug Administration may suspend and the Secretary may withdraw inspection service in any establishment:

(1) Upon failure of the packer to comply with any applicable provision of §§ 197.810 through 197.885; or

(2) Upon the dissemination by the packer or any person in privity with him of any representation that is false or misleading in any particular regarding the application to any seafood of the inspection service provided by the regulations in this part.

(b) When inspection service is suspended in an establishment, as authorized by paragraph (a) of this section, the Food and Drug Administration shall not lengthen the inspection period in such establishment to compensate for any of the time of suspension.

§ 197.820 Inspection periods.

(a) The regular inspection period in each establishment in which inspection service under §§ 197.810 through 197.885 is granted consists of 9 consecutive months. The date of the beginning of such regular inspection period shall be regarded as the date, on or after July 1, but not later than October 1, specified for the beginning of the service in the application therefor, or such other date as may be specified by amendment to such application and approved; but if the Secretary is not prepared to begin the service on the specified date, then the period shall start on the date on which service is begun.

(b) Extension inspection periods shall begin at the close of the preceding inspection period. Extension inspection periods may be granted for periods of 1 month and/or fractional parts of 1 month, but in no case less than 1 day. Extension inspection periods for 1 month may be granted in such establishment if application therefor, accompanied by a payment of $600.00 as prescribed by § 197.885(a)(3), is made at least 2 weeks in advance of the close of such preceding inspection period. Applications for extension inspection periods for fractional parts of a month may be accepted when accompanied by the payment prescribed by § 197.885(a)(3) for such extensions. No regular or extension inspection period shall extend beyond June 30 of any year.

(c) Upon request of the packer, and with the approval of the Food and Drug Administration, such service during any inspection period may be transferred from one establishment to another to be operated by the same packer; but such transfer shall not serve to lengthen any inspection period or to take the place of an extension inspection period. In case of such transfer the packer shall furnish all necessary transportation of inspectors.

(d) The inspection service shall be continuous throughout the inspection period.

§ 197.825 Assignment of inspectors.

(a) An initial assignment of at least one inspector shall be made to each establishment in which inspection service under §§ 197.810 through 197.885 is granted. Thereafter, the Food and Drug Administration shall adjust the number of inspectors assigned to each establishment and tour of duty of each inspector to the requirements for continuous and efficient inspection.

(b) Any inspector of the Food and Drug Administration shall have free access at all times to all parts of the establishment, to plants supplying materials to the inspected establishment, and to all fishing and freight boats and other conveyances catching shrimp for, or transporting shrimp to, such establishment.

§ 197.829 Uninspected shrimp excluded from inspected establishments.

(a) No establishment to which inspection service has been granted shall at any time thereafter process shrimp which has not been so inspected or handle or store in such establishment any processed shrimp which has not been so inspected; but this paragraph shall not apply to an establishment after termination of inspection service therein or withdrawal therefrom as authorized by § 197.815.

(b) All shrimp and other ingredients entering into the finished product may

be subject to inspection prior to delivery to the establishment or at any time thereafter, and all shrimp processed in such establishment shall be subject to certification under § 197.880.

§ 197.830 General requirements for plant and equipment.

(a) All exterior openings of the establishment shall be adequately screened and roofs and exterior walls shall be tight. When necessary, fly traps, fans, blowers, or other approved insect-control devices shall be installed.

(b) Except for raw headless shrimp which may or may not be deveined, picking and packing rooms shall be separate, provided that this requirement may be waived by the Food and Drug Administration where separation of picking and packing rooms is not necessary for adequate sanitation. Blanching tanks shall not be located in picking room. Fixtures and equipment shall be so constructed and arranged as to permit thorough cleaning. Such rooms shall be adequately lighted and ventilated, and the floors shall be tight and arranged for thorough cleaning and proper drainage. Open drains from picking room shall not enter packing or blanching room. If picking and packing rooms are in separate buildings, such buildings shall be not more than 100 yards apart unless adequate provisions are made to enable efficient inspection.

(c) All surfaces of tanks, belts, tables, flumes, utensils, and other equipment with which either picked or unpicked shrimp come in contact after delivery to the establishment shall be of metal or of other smooth nonporous and easily cleanable materials, provided such materials are not lead or other toxic substances. Metal seams shall be smoothly soldered or smoothly welded.

(d) Adequate supplies of suitable detergents and sanitizing agents approved by the Food and Drug Administration; clean, unpolluted running water; and, if necessary, steam shall be provided for washing, cleaning, and otherwise maintaining the establishment in a sanitary condition.

(e) Adequate toilet facilities of sanitary type which comply fully with applicable State laws and local ordinances shall be provided.

(f) An adequate number of sanitary washbasins, with liquid or powdered soap, shall be provided in both the picking and packing rooms. Paper towels shall be provided in the packing room. Provision shall be made for sanitizing the hands of employees by the use of suitable sanitizing agents.

(g) Signs requiring employees handling shrimp to wash and sanitize their hands after each absence from post of duty shall be conspicuously posted in the picking and packing rooms and elsewhere about the premises as conditions require.

(h) One or more suitable washing devices and one or more suitable inspection belts shall be installed for the washing and subsequent inspection of the shrimp before processing.

(i) Suitable containers, flumes, chutes, or conveyors shall be provided for removing offal from picking room.

(j) Picking or heading tables shall be equipped with flumes supplied with clean, unpolluted water or with mechanical conveyors for removing the picked or headed shrimp.

(k) Equipment shall be provided for code-marking cans and other immediate containers and master cartons used in packaging other than canned shrimp.

(l) An automatic container-counting device shall be installed in each cannery line.

(m) Each sterilizing retort shall be fitted with at least the following equipment:

(1) An automatic control for regulating temperatures.

(2) An indicating mercury thermometer of a range from 170° F to 270° F with scale divisions not greater than 2° F. For steam cook such thermometers shall be installed either within a fitting attached to the shell of the retort or within the door or shell of the retort. For water cook such thermometers shall be installed in the door or shell of the retort below the water level. If the thermometer is installed within a fitting such fitting shall communicate with the chamber of the retort through an opening at least 1 inch in diameter. Such fitting shall be equipped with a bleeder at least one-eighth of an inch in diameter. If the thermometer is installed within the door or shell of the retort, the bulb shall project at least two-thirds of its length into the principal chamber.

(3) A recording thermometer of a range from 170° F to 270° F with scale divisions not greater than 2° F. The bulb of such thermometer shall be installed as prescribed for the indicating mercury thermometer. The case which houses the charts and recording mechanism shall be provided with an approved lock, all keys to which shall be in the sole custody of the inspector.

(4) A pressure gauge of a range from 0 to 30 pounds, with scale divisions not greater than 1 pound and diameter of not less than 5 inches. Such gauge shall be connected to the chamber of the retort by a short gooseneck tube. The gauge shall be not more than 4 inches higher than the gooseneck.

(5) For steam cook, a blow-off vent of at least ¾-inch inside diameter in the top of the retort.

(6) For steam cook, a ⅛-inch bleeder in top of retort.

(n) Each cold storage compartment shall be fitted with at least the following equipment:

(1) An automatic control for regulating temperature.

(2) An indicating thermometer so installed as to indicate accurately the temperature within the storage compartment.

(3) A recording thermometer so installed as to indicate accurately the temperature within the compartment at all times. The case which houses the charts and recording mechanism shall be provided with an approved lock, all keys to which shall be in the sole custody of the inspector.

(o) Provision shall be made for water-glazing where such glazing is necessary to maintain the quality of frozen shrimp. Glazing shall be done with clean, unpolluted water.

(p) Provision shall be made for immediate icing or cold storage of all packaged shrimp which is destined for sale as unfrozen shrimp.

(q) Suitable space and facilities shall be provided for the inspector to prepare records and examine samples, and for the safekeeping of records and equipment.

§ 197.840 General operating conditions.

(a) Plants supplying raw headless or frozen raw headless shrimp to an inspected establishment, decks and holds of all boats catching shrimp for or transporting shrimp to an inspected establishment, and the bodies of other conveyances so transporting shrimp shall be kept in a sanitary condition.

(b) Inspected establishments, plants supplying inspected establishments, freight boats, and other conveyances serving such establishments shall accept only fresh, clean, sound shrimp. The shrimp shall be iced or refrigerated immediately after they are caught, and shall be kept adequately iced or refrigerated until delivery to the establishment.

(c) After delivery of each load of shrimp to the establishment, decks and holds of each boat and the body of each other conveyance or container making such delivery shall be washed down with clean, unpolluted water, and all debris shall be cleaned therefrom before such boat or other conveyance or container leaves the establishment premises.

(d) Before being headed, picked, or deveined, the shrimp shall be adequately washed with clean, unpolluted water and then passed over the inspection belt and culled to remove all shrimp that are filthy, decomposed, putrid, or otherwise unfit for food, and all extraneous material.

(e) Offal from picking tables shall not be piled on the floor, but shall be placed in suitable containers for frequent removal, or shall be removed by flumes, conveyors, or chutes. Offal, debris, or refuse from any source whatever shall not be allowed to accumulate in or about the establishment.

(f) Shrimp shall be picked into flumes that immediately remove the picked meats from the picking tables; except that shrimp may be picked into seamless containers of not more than 3 pints capacity if the picked meats are not held in such containers for more than 20 minutes before being flumed or conveyed from the picking tables. If shrimp are picked into such containers, the containers shall be cleaned and sanitized as often as may be necessary to maintain them in a sanitary condition, but in no case less frequently than every 2 hours. Whenever a picker is absent from his or her post of duty, the container used by such picker shall be cleaned and sanitized before picking is resumed. For the

purposes of this paragraph, the term "picked" shall include the operation whereby a portion of the shell is removed, leaving the tail in place, and the back of the shrimp is sliced open to remove the alimentary canal or vein.

(g) Picked shrimp being transported from one building to another shall be properly covered and protected against contamination.

(h) From the time of delivery to the establishment up to the time of final processing, shrimp shall be handled expeditiously and under such conditions as to prevent contamination or spoilage. Shrimp other than that to be canned shall be precooled immediately after the final cleaning or blanching operation to a temperature not exceeding 50° F if it is to be packaged immediately, or to a temperature not exceeding 40° F if it is not to be packaged immediately. If such shrimp are to be frozen, they shall be placed in the freezing compartment within 1 hour after final preparation.

(i) If batter is employed, it shall be used within 1 hour after it is prepared. The temperature of the batter shall not exceed 50° F.

(j) The packer shall destroy for food purposes under the immediate supervision of the inspector all shrimp in his possession condemned by the inspector as filthy, decomposed, putrid, or otherwise unfit for food. Shrimp condemned on boat or unloading platform shall not be taken into the icebox or picking room.

(k) Raw materials other than shrimp that enter into the finish product shall not be used if condemned by the inspector as unfit for food. Such condemned raw materials shall be segregated from usable materials and be held for disposal as directed by the inspector, or they may be destroyed forthwith by the packer if he so desires.

(l) All portions of the establishment shall be adequately lighted to enable the inspector to perform his duties properly.

(m) All floors and other parts of the establishment, including unloading platforms, and all fixtures, equipment, and utensils shall be cleaned as often as may be necessary to maintain them in a sanitary condition. Containers for mixing or holding batter shall be adequately cleaned and sanitized before they are used for a new batch of batter. Equipment for applying batter shall be adequately cleaned and sanitized at least once each hour while in operation.

(n) The packer shall require all employees handling shrimp to wash and sanitize their hands after each absence from post of duty, and to observe other proper habits of cleanliness.

(o) The packer shall not knowingly employ in or about the establishment any person afflicted with an infectious or contagious disease, or with any open sores on exposed portions of the body.

§ 197.850 Code marking.

(a) Permanently legible code marks shall be placed on all immediate containers at the time of packaging. Such marks shall show at least:

(1) The date of packing;

(2) The establishment where packed; and

(3) The size of the shrimp when such shrimp are graded for size and are not in containers through which they are clearly visible.

Corresponding code marks shall also be placed on the master cartons containing individual packages of shrimp other than canned.

(b) Keys to all code marks shall be given to the inspector.

(c) Each lot shall be stored separately pending final inspection, with a space of not less than 6 inches between stacks of each lot. For the purposes of the regulations in this part, all cans or other containers bearing the same code marks shall be regarded as comprising a lot.

§ 197.855 Processing.

(a) The closure of the can or other immediate container and the time and temperature of sterilizing the canned shrimp shall be adequate to prevent bacterial spoilage.

(b) The following times and temperatures shall be the minimums employed for the containers indicated:

Dry pack

Kind of container and liner	Size	Initial temperature	Time at 240° F	Time at 250° F
			Minutes	*Minutes*
Tin:				
1-piece liner	211 by 400 and smaller.	70° F	80	60
No liner	do	70° F	75	50
	307 by 208	70° F	70	50
	307 by 400	70° F	75	55

Wet pack

Kind of container and size	Initial temperature	Time at 240° F	Time at 250° F
		Minutes	*Minutes*
Tin:			
211 by 400 (and smaller)	90° F	25	13
307 by 208	90° F	25	13
307 by 400	90° F	25	13
502 by 510	90° F	27	16
Glass: 2 to 9 fluid ounces, inclusive.		22	14

For wet-pack shrimp in cans 307 x 400 and smaller, a cook of 12 minutes at 250° F, and for wet-pack shrimp in cans 502 x 510, a cook of 15 minutes at 250° F, may be approved if adequate provisions are made to insure an initial temperature of not less than 120° F in each individual can. For the purposes of this section, initial temperature is defined as the average temperature of the contents of the container at the moment steam is admitted to the sterilizing retort.

(c) For steam cook, blow-off vent shall be open during the coming-up period until the mercury thermometer registers at least 215° F. Bleeders shall emit steam during the entire cooking period.

(d) The method of freezing is not specified by the regulations in this part. Whatever method is used must be such as will produce a hard-frozen product in a sufficiently short time to prevent decomposition. Bulk packages containing 5 pounds or more of shrimp per package shall be hard frozen within 24 hours; smaller packages should be hard frozen within 12 hours. After freezing, the shrimp shall be stored in such a manner that its temperature does not exceed 0° F, and shall be handled in such manner as will maintain the hard-frozen condition.

(e) The storage temperatures for shrimp that are not frozen or canned are as follows:

(1) Cooked and peeled shrimp shall be stored at a room temperature not exceeding 35° F.

(2) Raw headless shrimp shall be stored at a room temperature not exceeding 35° F, except that it may be stored at a higher room temperature if sufficiently iced at all times to prevent spoilage.

(f) The inspector shall identify each record on the thermometer chart with the code mark of the lot to which such record relates and the date of such record. The Food and Drug Administration shall keep such charts for at least 5 years, and upon request shall make them available to the packer.

(g) The packer shall keep for at least 2 years all shipping records covering shipments from each lot, and upon request shall furnish such records to any inspector of the Food and Drug Administration.

§ 197.860 Examination after processing.

(a) Adequate samples shall be drawn by the inspector from each lot of processed shrimp and shall be examined to determine whether or not such processed shrimp conforms to all requirements of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder.

(b) The packer shall destroy for food purposes, under the immediate supervision of the inspector, all processed shrimp condemned by the inspector as not complying with § 197.855(a), or as filthy, decomposed, putrid, or otherwise unfit for food.

§ 197.870 Labeling.

(a) Labels on shrimp packed and certified under §§ 197.810 through 197.885 may bear a mark attesting to such packing and certification. Depending upon the type of processing, such marks, if used, shall read as follows:

(1) For canned shrimp: "Production supervised by U.S. Food and Drug Administration."

(2) For frozen shrimp: "Packing and freezing supervised by U.S. Food and Drug Administration. Perishable product—Not warranted against mishandling after freezing."

(3) For fresh, iced, or refrigerated shrimp: "Packing supervised by U.S. Food and Drug Administration. Perishable product—Not warranted against mishandling after packing."

Such marks if used shall be plainly and conspicuously displayed in type of uniform size and style on a strongly contrasting uniform background. The marks referred to in paragraph (a)(2) and (3) of this section shall not be used on the master carton unless such marks will be defaced by the opening of the cartons.

(b) Labels on inspected processed shrimp, other than canned shrimp, not bearing the marks referred to in paragraph (a) (2) and (3) of this section, and all master cartons for inspected shrimp other than canned shrimp, shall bear the statement "Perishable—Keep frozen" or "Perishable—Keep refrigerated," whichever is applicable to the product.

(c) Two proofs, or one proof and one photostat thereof, or eight specimens of all labeling intended for use on inspected shrimp, or on or within the cases therefor, shall be submitted to the Food and Drug Administration for approval. If proofs or photostat and proof are submitted, eight specimens of the labeling shall be sent to the Food and Drug Administration after printing. The Food and Drug Administration is authorized to approve labeling for use on or with processed shrimp inspected under §§ 197.810 through 197.885; approval shall be subject to the condition that such labeling shall be so used as to comply with the provisions of the Federal Food, Drug, and Cosmetic Act, amendments thereto and regulations thereunder. The Food and Drug Administration is also authorized to revoke any such approval for cause. The Food and Drug Administration shall not approve labeling for processed shrimp intended for export under the provisions of § 197.880(e).

(d) No commercial brand or brand name appearing on labeling approved as authorized under paragraph (c) of this section and bearing the marks described in paragraph (a) of this section, and no labeling simulating any such approved labeling, shall be used, after such approval, on processed shrimp other than that which has been handled, prepared, packed, and stored in compliance with all provisions of §§ 197.810 through 197.885; but this section shall not apply to any packer's labeling not bearing such mark after termination of inspection or withdrawal thereof as authorized by § 197.815 or to any distributor's labeling not bearing such mark after written notice by the owner thereof to the Food and Drug Administration that the use of such labeling on inspected processed shimp has been discontinued and will not be resumed.

(e) Shrimp labeling authorized by paragraph (a) of this section or approved under paragraph (c) of this section shall be used only as authorized by §§ 197.810 through 197.885. Unauthorized use of such labeling renders the user liable to the penalties prescribed by the Federal Food, Drug, and Cosmetic Act, as amended.

§ 197.880 Certificates of inspection; warehousing and export permits.

(a) After finding that the processed shrimp comprising any parcel has been handled, prepared, and packed in compliance with all provisions of §§ 197.810 through 197.885, bears labeling approved as authorized under § 197.870(c), and complies with all the provisions of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder, the inspector shall issue a certificate showing that such processed shrimp so complies. The certificate shall specify the code marks to which it applies, the quantity of the parcel so marked, the place where such parcel is stored, the size of the shrimp, the size and kind of containers, the type of pack, the commercial brand name on the labels, the quality grade of the shrimp if it is fancy, the condition of the shrimp if it is broken or if it is substandard in fill and the destination of the lot if known. Such certificate shall become void if such labeling is removed, altered, obliterated, or replaced, or if mishandling, improper storage, or other circumstances so change the product that it no longer complies with the requirements for the issuance of a certificate; but such processed shrimp may be relabeled under the supervision of an inspector and recertified if the inspector finds that, after being relabeled, it complies with the requirements laid down by this paragraph for the issuance of a certificate.

(b) Unless covered by certificate, processed shrimp shall be moved from an inspected establishment only for storage authorized under paragraph (c) of this section, or for export authorized under paragraph (e) of this section, or for destruction as provided by § 197.860(b).

(c) Applications to move unlabeled processed shrimp for storage in a warehouse or cold storage plant elsewhere than in the establishment where such shrimp was processed shall be on forms supplied by the Food and Drug Administration. The application shall give the name and location of the warehouse or cold storage plant in which such processed shrimp is to be stored, and shall be accompanied by an agreement signed by the operator of such warehouse or cold storage plant that inspectors shall have free access at all times to all processed shrimp so stored and that conditions which will preserve the identity of each parcel of such processed shrimp shall be continuously maintained pending issuance of a certificate thereon or removal as authorized by paragraph (d) of this section. If such application is approved and it appears to the inspector that the processed shrimp comprising any parcel has been packed in compliance with §§ 197.810 through 197.885 and conforms, except for the absence of labeling, to all requirements of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder, the inspector shall issue to the applicant, on his request, a warehousing permit covering such processed shrimp. Such permit shall specify the code marks to which it applies, the quantity of the parcel so marked, the places from and to which such parcel is to be moved, the size of the shrimp, the size and kind of containers, the type of pack, whether or not it is fancy grade, the condition of the shrimp if it is broken or if it is substandard in fill, and, if such be the case, that it is intended for export under paragraph (e) of this section. When any provision of the agreement is violated, the Food and Drug Administration may revoke any permit issued pursuant to such agreement, and may also revoke its approval of the application for warehousing or cold storage which accompanied such agreement.

(d) Unless covered by certificate, processed shrimp stored under the authority of paragraph (c) of this section shall be moved from the warehouse or cold storage plant where stored only for re-storage under such authority, or for return upon written permission of the inspector to the establishment where processed, or for export authorized under paragraph (e) of this section, or for destruction as provided by § 197.860(b).

(e) An application to export processed shrimp under the provisions of section 801(d) of the act shall be accompanied by the original or a verified copy of the specifications of the foreign purchaser; if required by the Food and Drug Administration, evidence showing that such processed shrimp is not in conflict with the laws of the country to which it is intended for export; and, if shipment of labeled processed shrimp is specified or directed, eight specimens of the labeling therefor. If processed shrimp prepared or packed according to such specifications is not in conflict with the laws of such country, the Food and Drug Administration shall direct the inspector to issue to the applicant an export permit covering such processed shrimp comprising any parcel ordered by such purchaser under such specifications when the inspector finds that such processed shrimp was packed in compliance with the requirements of §§ 197.810 through 197.885 regarding sanitary conditions and processing; is not filthy, decomposed, putrid, or otherwise unfit for food, accords to such specifications; and is labeled on the outside of the shipping package to show that it is intended for export. Such permit shall specify the code marks to which it applies and the quantity of the parcel so marked, and shall show that such processed shrimp was packed under sanitary conditions, is wholesome, and accords to such specifications. The applicant shall furnish to the inspector documentary evidence showing the exportation of all such processed shrimp.

§ 197.885 Inspection fees.

(a)(1) Except as otherwise provided by the regulations in this part, an initial payment of $500.00 shall accompany each application; thereafter, eight addi-

tional advance payments of $500.00 shall be made on or before the first day of each month beginning July 1 and continuing through February 1 for the regular inspection period; except that the Food and Drug Administration may require the full amount of advance payments prescribed by this paragraph to accompany the application of an applicant who has defaulted in any payment due for any prior packing season.

(2) Whenever it is determined, without hearing, by the Food and Drug Administration that an establishment having the inspection service has been damaged by wind, fire, flood, or other calamity, to such an extent that packing operations cannot be resumed before the end of the fiscal year then current, no advance payments falling due after such calamity shall be required from the packer for that fiscal year; but whenever it is determined, without hearing, by the Food and Drug Administration that an establishment having the inspection service has been so damaged by any such calamity that operations must be suspended temporarily, but can be resumed before the end of the fiscal year then current, advance payments falling due after such calamity and before the month of resumption of operations shall be postponed until operations are resumed, and thereupon shall be paid in equal monthly installments during the period between the time of resumption of operations and June 1 of the fiscal year then current: *Provided*, That in the event of a determination described in paragraph (a)(2) of this section the total payments and deposits made by the packer involved shall be charged with the cost of the service made available for the establishment without regard to the method provided hereinafter for computing charges against payments and deposits for shrimp received, and the balance of the total payments and deposits for shrimp received remaining after such charges shall be refunded by the Administration to the packer after the completion of the fiscal year.

(3) Each application for an extension inspection period of 1 month shall be accompanied by a payment of $600.00, and at subsequent monthly intervals thereafter additional payments of $600.00 shall be made; but if the final payment is to cover a period of less than 30 days, then such payment shall be at the rate of $20.00 for each day of such period.

(b)(1) In addition to the payments prescribed in paragraph (a) of this section, advance deposits based upon the quantity of shrimp received by the subscribing establishment shall be made to underwrite adequately the cost of the inspection service. Such deposits shall be paid in advance in amounts of not less than $300.00, unless the Food and Drug Administration on an estimate of receipt of shrimp authorizes other amounts, and shall be computed at the rate of 20 cents per 100 pounds of whole raw shrimp, or 35 cents per 100 pounds of raw headless shrimp, received by the plant. For the purposes of this section, the quantity of shrimp received by an establishment shall be determined by weighing on a suitable scale immediately after such shrimp leaves the initial inspection belt: *Provided, however*, That other arrangements for determining accurately the weight of shrimp received may be employed if approved in advance by the Food and Drug Administration. A record of such weights shall be maintained and made available to the inspector upon his request. Any advance deposits in excess of those required for actual shrimp received for the fiscal year (July 1 through June 30) shall be refunded to the packer by the Food and Drug Administration after the completion of the fiscal year.

(2) Deposits for shrimp received as computed under paragraph (b)(1) of this section, together with production deposits prescribed for oysters canned under § 197.385(b)(1), shall be charged with the balance of the total cost of the inspection service that has not been provided for by the combined total payments under paragraph (a) of this section and § 197.385(a), in the case of canned oysters. The balance of the deposits remaining for shrimp received after such charges have been made shall be refunded by the Food and Drug Administration to the packers after the completion of the fiscal year, in the ratio which each packer's deposits for shrimp received and production deposits for oysters canned bears to the combined total of such deposits for shrimp received and oysters canned by all packers for the fiscal year.

(3) When inspection service is withdrawn from an establishment as authorized under § 197.815(a), the Food and Drug Administration shall not return to the packer any advance payments and/or deposits required to the date of withdrawal of the service. Such payments and/or deposits shall be charged with the cost of the service made available for the establishment, without regard to the method described in this section, and the balance which would have accrued to such packer shall remain to the credit of the Food and Drug Administration in the special account "Salaries and Expenses, Certification and Inspection Services."

(c) A separate fee shall be paid to cover all expenses, incurred in accordance with the regulations of the United States Government for salary, travel, subsistence, and other purposes incident to inspection described under § 197.825 (b) of suppliers of any materials to establishments under the inspection service or for the purpose of issuing a certificate or warehousing or export permit on processed shrimp stored or held at any place other than an establishment to which a seafood inspector is then assigned.

(d) When the processing plant and the warehouse or cold storage plant of an establishment are located at different points of such distance apart that transportation between them is required for the inspector to perform his duties in the establishment, the packer shall furnish such transportation or shall pay a separate fee to cover all expenses therefor.

(e) All payments required by the regulations in this part shall be by bank draft or certified check collectible at par drawn to the order of the Food and Drug Administration, and payable at Washington, DC. All such drafts and checks, except those for the payment required by § 197.810(a), shall be delivered to the inspector and promptly scheduled to the Food and Drug Administration, Department of Health, Education, and Welfare, Washington, DC, whereupon after appropriate records thereof have been made, they shall be transmitted to the Chief Disbursing Officer, Division of Disbursement, Treasury Department, for deposit to the special account, "Certification and Inspection Services, Food and Drug Administration."

(f) All refunds to the packers shall be by check drawn on the Treasury of the United States pursuant to refund vouchers duly certified and approved by the designated administrative officers.

[FR Doc.77-7048 Filed 3-14-77;8:45 am]

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